

EXAMINING HRSA'S OVERSIGHT OF THE 340B DRUG PRICING PROGRAM

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

JULY 18, 2017

Serial No. 115-46



Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

26-929

WASHINGTON : 2018

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

COMMITTEE ON ENERGY AND COMMERCE

GREG WALDEN, Oregon
Chairman

JOE BARTON, Texas <i>Vice Chairman</i>	FRANK PALLONE, JR., New Jersey <i>Ranking Member</i>
FRED UPTON, Michigan	BOBBY L. RUSH, Illinois
JOHN SHIMKUS, Illinois	ANNA G. ESHOO, California
TIM MURPHY, Pennsylvania	ELIOT L. ENGEL, New York
MICHAEL C. BURGESS, Texas	GENE GREEN, Texas
MARSHA BLACKBURN, Tennessee	DIANA DEGETTE, Colorado
STEVE SCALISE, Louisiana	MICHAEL F. DOYLE, Pennsylvania
ROBERT E. LATTA, Ohio	JANICE D. SCHAKOWSKY, Illinois
CATHY McMORRIS RODGERS, Washington	G.K. BUTTERFIELD, North Carolina
GREGG HARPER, Mississippi	DORIS O. MATSUI, California
LEONARD LANCE, New Jersey	KATHY CASTOR, Florida
BRETT GUTHRIE, Kentucky	JOHN P. SARBANES, Maryland
PETE OLSON, Texas	JERRY McNERNEY, California
DAVID B. MCKINLEY, West Virginia	PETER WELCH, Vermont
ADAM KINZINGER, Illinois	BEN RAY LUJAN, New Mexico
H. MORGAN GRIFFITH, Virginia	PAUL TONKO, New York
GUS M. BILIRAKIS, Florida	YVETTE D. CLARKE, New York
BILL JOHNSON, Ohio	DAVID LOEBSACK, Iowa
BILLY LONG, Missouri	KURT SCHRADER, Oregon
LARRY BUCSHON, Indiana	JOSEPH P. KENNEDY, III, Massachusetts
BILL FLORES, Texas	TONY CARDENAS, California
SUSAN W. BROOKS, Indiana	RAUL RUIZ, California
MARKWAYNE MULLIN, Oklahoma	SCOTT H. PETERS, California
RICHARD HUDSON, North Carolina	DEBBIE DINGELL, Michigan
CHRIS COLLINS, New York	
KEVIN CRAMER, North Dakota	
TIM WALBERG, Michigan	
MIMI WALTERS, California	
RYAN A. COSTELLO, Pennsylvania	
EARL L. "BUDDY" CARTER, Georgia	

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

TIM MURPHY, Pennsylvania
Chairman

H. MORGAN GRIFFITH, Virginia <i>Vice Chairman</i>	DIANA DEGETTE, Colorado <i>Ranking Member</i>
JOE BARTON, Texas	JANICE D. SCHAKOWSKY, Illinois
MICHAEL C. BURGESS, Texas	KATHY CASTOR, Florida
SUSAN W. BROOKS, Indiana	PAUL TONKO, New York
CHRIS COLLINS, New York	YVETTE D. CLARKE, New York
TIM WALBERG, Michigan	RAUL RUIZ, California
MIMI WALTERS, California	SCOTT H. PETERS, California
RYAN A. COSTELLO, Pennsylvania	FRANK PALLONE, JR., New Jersey (<i>ex officio</i>)
EARL L. "BUDDY" CARTER, Georgia	
GREG WALDEN, Oregon (<i>ex officio</i>)	

CONTENTS

	Page
Hon. Tim Murphy, a Representative in Congress from the Commonwealth of Pennsylvania, opening statement	1
Prepared statement	3
Hon. Diana DeGette, a Representative in Congress from the state of Colorado, opening statement	4
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	6
Prepared statement	8
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	9

WITNESSES

Capt. Krista M. Pedley, PHARMD, MS, Director, Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services	11
Prepared statement	14
Answers to submitted questions	96
Erin Bliss, Assistant Inspector General, Office of Evaluation And Inspections, Office of Inspector General, U.S. Department of Health and Human Services	20
Prepared statement	22
Answers to submitted questions	102
Debra Draper, Director, Health Care, Government Accountability Office	31
Prepared statement	33

SUBMITTED MATERIAL

Subcommittee memorandum	82
-------------------------------	----

EXAMINING HRSA'S OVERSIGHT OF THE 340B DRUG PRICING PROGRAM

TUESDAY, JULY 18, 2017

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:18 a.m., in room 2322 Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Present: Representatives Murphy, Griffith, Burgess, Brooks, Collins, Barton, Walberg, Walters, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Clarke, Ruiz, Peters, and Pallone (ex officio).

Staff present: Ali Fulling, Legislative Clerk, Oversight and Investigations; Brighton Haslett, Counsel, Oversight and Investigations; Brittany Havens, Professional Staff, Oversight and Investigations; Katie McKeogh, Press Assistant; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Sam Spector, Policy Coordinator, Oversight and Investigations; Josh Trent, Deputy Chief Health Counsel, Health; Natalie Turner, Counsel, Oversight and Investigations; Christina Calce, Minority Counsel; Jeff Carroll, Minority Staff Director; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; Rachel Pryor, Minority Senior Health Policy Advisor; and C. J. Young, Minority Press Secretary.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY. Good morning.

Today's Subcommittee on Oversight and Investigation is holding a hearing entitled, "Examining HRSA's Oversight of the 340B Drug Pricing Program." The 340B program was created by Congress in 1992 and mandates that drug manufacturers provide outpatient drugs to eligible entities at reduced prices in order for the manufacturers to remain eligible for reimbursement through entitlement programs such as Medicaid and Medicare.

Now, the 340B program covers entities, which are like hospitals and other nonprofit health care organizations, that have certain federal designations or receive funding from specific federal programs. They are eligible for the 340B program by receiving certain federal grants administered by different agencies within HHS. Hos-

pitals eligible for the 340B program include certain disproportionate share hospitals, children's hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals.

The Health Resources and Services Administration, or HRSA, an agency in the U.S. Department of Health and Human Services is tasked with accepting applications and overseeing the covered hospitals and clinics.

HRSA faces several challenges in conducting oversight of the 340B program, one of which is the lack of reporting requirements in the 340B statute. Participating hospitals save between 25 to 50 percent of the average wholesale price for covered outpatient drugs. They saved \$6 billion on drug expenditures in fiscal year 2016, according to the HHS Office of Inspector General estimates. Hospitals are not required to report their annual savings through participation in the program or how they use the money saved.

For many of these covered entities, those savings are vital to the entities' survival, particularly those that serve a large percentage of indigent patients and operate at a loss each year. Other entities reinvest those savings in patient care, expanding access to patient care by opening centers in rural and underserved areas or passing along the savings to patients by providing discounted drugs. However, as with so many federal programs, there are instances of errors and misuse.

Specialists, oncologists in particular, have told stories to us of their grave concerns about the way some entities use the 340B program. For example, one store involves a doctor who referred many uninsured young breast cancer patients to a 340B hospital to receive cancer treatments but watched as 16 of those patients were placed on a wait list for care, simply waiting for treatment while their cancer progressed from entirely treatable to potentially life threatening. According to this doctor, the wait list was not due to an overall capacity issue. Instead, it was because the hospital simply chose to set a cap on the number of uninsured patients they would treat.

I hope that instances like this are outliers—the exception to the rule. The integrity of the 340B program must be protected. HRSA must be able to conduct oversight in a way that allows it to uncover fraud and noncompliance. Indeed, HRSA audits from fiscal year 2012 to fiscal year 2016 demonstrate that noncomplying entities violate program requirements through duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting. Unfortunately, while HRSA has made improvements to their oversight efforts in recent years, the agency simply may not have the resources to adequately safeguard the program.

The program has experienced dramatic growth in recent years, due in part to program expansions in the patient protections in the Affordable Care Act. At a hearing before the Health subcommittee in 2015 we learned that from 2001 to 2011 the number of covered entities participating in the program roughly doubled. The most recent data shows that from 2011 to 2017 the number of entities has nearly quadrupled. HRSA indicates that as of October 2016, 12,148 covered entities were participating in the 340B program.

Despite that growth, HRSA maintains only 22 staff to oversee the 340B program and conducts roughly 200 audits per year. While HRSA has increased the number of audits conducted annually, which the committee applauds HRSA for, that number is still dwarfed by the vast number of participating entities and manufacturers. Now, listen to this. At the current level of annual audits conducted, HRSA is auditing a mere 1.6 percent covered entities. That's 1.6 percent. That is all. Further, because HRSA's audits consist of only a sample of drugs within each entity, these audits cover just a fraction of a fraction of the program. Despite that, HRSA's audits have uncovered between 63 and 82 percent of audited entities to be noncompliant with program requirements since 2012. Needless to say, that is a concern. What would more intensive oversight including additional audits further reveal? What is the outcome if the hospital is found to be in noncompliance with diversion, duplication, or incorrect data?

Well, nothing. No one has ever lost a 340B eligibility because of these problems. I thank HRSA for their cooperation for using audit documents before this hearing in response to the committee's request last month.

We are in the process of reviewing these documents to gain a better understanding of the audit process and may have more follow-up questions at a later date.

Now, I am a big supporter of the 340B program. I will continue to defend them. But I don't buy the argument that some have presented to me that says show me someone who got caught, because chances are 94 percent that no one is even going to look at you, and so you won't be audited, and 100 percent chance that nothing is going to happen afterwards. That is why we are here, to find out is there a concern or not a concern.

And we welcome all the witnesses today too and look forward to hearing HRSA's oversight efforts, the challenges HRSA faces and how this committee can best enable HRSA to overcome these challenges.

I now yield 5 minutes to Ms. DeGette.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

Today, the subcommittee is holding a hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program." The 340B program was created by Congress in 1992 and mandates that drug manufacturers provide outpatient drugs to eligible entities at reduced prices in order for the manufacturers to remain eligible for reimbursements through entitlement programs such as Medicaid and Medicare.

340B program-covered entities are nonprofit health care organizations that have certain federal designations or receive funding from specific federal programs. Federal grantees are eligible for the 340B program by receiving certain federal grants administered by different agencies within HHS. Hospitals eligible for the 340B program include certain Disproportionate Share Hospitals, children's hospitals, free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals.

The Health Resources and Services Administration, or "HRSA," an agency in the U.S. Department of Health and Human Services, is tasked with accepting applications and overseeing covered entities.

HRSA faces several challenges in conducting oversight of the 340B program, one of which is the lack of reporting requirements in the 340B statute. Participating entities save between 25–50 percent of the average wholesale price for covered outpatient drugs, and according to the HHS Office of Inspector General's estimates,

covered entities saved \$6 billion on drug expenditures in Fiscal Year 2016. However, covered entities are not required to report their annual savings through participation in the program, or how they use the money saved.

For many of these covered entities, those savings are vital to the entity's survival, particularly those that serve a large percentage of indigent patients and operate at a loss each year. Other entities reinvest those savings in patient care, expanding access to patient care by opening centers in rural and underserved areas or passing along the savings to patients by providing discounted drugs. However, as with so many federal programs, there are instances of errors and misuse.

Specialists, oncologists in particular, have told me stories of their grave concerns about the way some entities use the 340B program. For example, one story involves a doctor who referred many uninsured, young breast cancer patients to a 340B hospital to receive cancer treatments, but watched as 16 of those patients were placed on a waitlist for care, simply waiting for treatment while their cancer progressed from entirely treatable, to potentially life-threatening. According to this doctor, the waitlist was not due to an overall capacity issue. Instead, it was because the hospital simply chose to set a cap on the number of uninsured patients they would treat.

I hope that these instances are outliers—the exception to the rule. The integrity of the 340B program must be protected. HRSA must be able to conduct oversight in a way that allows it to uncover fraud and non-compliance. Indeed, HRSA audits from FY 2012 to FY 2016 demonstrate that non-complying entities violate program requirements through duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting. Unfortunately, while HRSA has made improvements to their oversight efforts in recent years, the agency simply may not have the resources to adequately safeguard the program.

The program has experienced dramatic growth in recent years, due in part to program expansions in the Patient Protection and Affordable Care Act. At a hearing before the Health Subcommittee in 2015, we learned that from 2001 to 2011, the number of covered entities participating in the program roughly doubled. The most recent data shows that from 2011 to 2017, the number of entities has nearly quadrupled. HRSA indicates that as of October 2016, 12,148 covered entities were participating in the 340B program.

Despite that growth, HRSA maintains only 22 staff to oversee the 340B program, and conducts roughly 200 audits annually. While HRSA has increased the number of audits conducted annually, which the Committee applauds HRSA for, that number is still dwarfed by the vast number of participating entities and manufacturers. At the current level of annual audits conducted, HRSA is auditing a mere 1.6% of covered entities annually. Further, because HRSA's audits consist of only a sample of drugs within each entity, these audits cover just a fraction of a fraction of the program. Despite that, HRSA's audits have uncovered between 63 and 82 percent of audited entities to be non-compliant with program requirements since 2012. What would more intensive oversight, including additional audits, further reveal?

I thank HRSA for their cooperation in producing audit documents before this hearing in response to the Committee's request last month. We're in the process of reviewing these documents to gain a better understanding of the audit process and may have more follow-up questions at a later date.

I welcome the witnesses appearing before us today and look forward to hearing about HRSA's oversight efforts, the challenges HRSA faces, and how this committee can best enable HRSA to overcome those challenges.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman.

Mr. Chairman, Congress created the 340B drug discount program 25 years ago to help safety net providers leverage their scarce resources to serve more people, especially people in low-income and vulnerable areas. Thanks to this program, providers across the country have been able to purchase discounted pharmaceuticals and expand and improve their services.

I think we can stipulate that 340B is critical to provide critical medical services to low-income people. But we also can stipulate that we need to make sure that our oversight remains robust.

340B drug discounts allow eligible hospitals and other designated providers including community health centers, state and local health departments and family clinics to make the most of their limited resources. But as the Government Accountability Office and the HHS Office of Inspector General have found, there is a need for more oversight of this important program to ensure that it achieves its critical mission.

GAO and OIG have conducted several reviews of the 340B program and have repeatedly underscored that it needs more effective oversight. Of course, to conduct that oversight, HRSA must have the tools it needs to implement better controls over the program. These tools may require additional authority from Congress, which I would like to explore today, and also, given the size of the agency, if you want more robust oversight you are going to have to give more funding.

I also want to point out, Mr. Chairman, that I am troubled by the rule that the Centers for Medicare and Medicaid proposed last week which would dramatically reduce reimbursements to Medicare Part B drugs for 340B hospitals. The Trump administration claimed that this proposed rule was an important step to lower the cost of drugs to the American people. Unfortunately, that statement seems more fantasy than reality.

The proposed rule will do nothing to achieve the goal of making prescription drugs more affordable to the general population. Reducing the repayment rate that 340B hospitals receive for Medicare Part B drugs does nothing to get to the root of high drug prices, and frankly, it tries to solve one problem by creating many others. Rather than rolling up its sleeve and attempting to address the actual cost of high drug prices, the administration's proposed rule instead threatens to undermine the important safety net mission of 340B hospitals.

Many 340B hospitals are what are called disproportionate share safety net hospitals—the DSH hospitals. This means they often serve low-income and rural communities and take on patients other parts of the health care system either cannot or will not impact. In my district in Denver, Colorado, we have a number of these DSH hospitals including St. Joseph Hospital, which is a part of SCL Health, and SCL Health operates six other 340B hospitals and provides essential often uncompensated care which 340B drug discounts have helped to fund.

Now, the reduced payment rate pulls the rug out from under providers like St. Jo's and puts the patients they serve at risk of losing access to care. As you know, Mr. Chairman, many of my colleagues and I have asked this subcommittee to open an investigation into why drug prices are so high and how we can address this problem.

I think we need a robust investigation and a series of hearings that explore in-depth the reasons for exorbitant costs of drugs and why the prices continue to rise.

Unfortunately, I don't think this hearing nor the rule proposed by CMS last week addresses the broad problem of high drug prices. I know that all of us are dedicated to ensuring that the 340B pro-

gram achieves its critical mission of helping providers serve the indigent. I want to make sure, like you do, that sound controls are in place to prevent abuse.

And, Mr. Chairman, while I am glad to work with you to address some of the problems of the 340B program, the concerns associated with it are fundamentally separate from the high cost of drugs in the U.S. and I believe the issue should be treated differently. Put simply, the committee should hold hearings, we should take meaningful action on the high cost of drugs and the rising costs. In the meantime, I look forward to hearing from the witnesses today about what we can do to strengthen our safety net and to improve HRSA's oversight of the 340B program.

With that, I yield back. Thanks.

Mr. MURPHY. The gentlelady yields back.

I now recognize the chairman of the full committee, Mr. Walden.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Mr. Chairman, for this hearing. The committee is already ramped up its top to bottom oversight of many aspects of the cost drivers in our health care system and we have more work to do.

The subcommittee's hearing on 340B drug pricing program and the oversight role of the Health Resources and Services Administration, or HRSA, is part of this broader review and we appreciate our witnesses here today.

Since its creation by Congress in 1992, the 340B drug pricing program has provided lifesaving medicines at reduced prices to certain safety net health care providers. Indeed, this program has helped these providers, known as covered entities, stretch scarce federal dollars as far as possible to better serve uninsured and under insured patients across the country. HRSA estimated that in 2015 covered entities saved about \$6 billion on 340B drugs through their participation in the program.

For a variety of reasons, participation by hospitals in the 340B program has grown substantially in recent years and the number of unique hospital organizations participating in the program has nearly quadrupled from 2011 to 2016, increasing from 3,200 participating hospitals in 2011 to 12,148 as of October of 2016.

Now, with this growth concerns have been raised about HRSA's ability to adequately oversee this program, as the witnesses from HHS Inspector General's office and GAO will discuss in detail today. HRSA's oversight of the program has improved in recent years through enhanced authority and resources but program vulnerabilities still exist. So today we will examine a number of important programmatic issues.

First, we want to learn how HRSA's oversight efforts can best meet the challenges of 340B growth. While HRSA has made improvements to its oversight efforts in recent years, HRSA's audit activities remain at or below 200 annual audits of covered entities since 2012, despite the rapid growth of the program. That is one reason we are here today. That is to answer the question: How can HRSA improve its audits to better detect problems or somehow raise the annual number of audits?

Next, we will focus on the problems already discovered and how HRSA can address them. HRSA's annual audits reveal a high level of noncompliance with program requirements by covered entities including the potential for duplicate discounts and diversion of 340B drugs to ineligible patients.

We will also want to find out how HRSA can be more transparent. Lack of transparency hinders HRSA's oversight capabilities, and while the purpose of the program is to stretch scarce resources as far as possible, reaching more eligible patients, and providing more comprehensive services, neither 340B nor HRSA guidance explains how 340B providers must use savings from the program. That is an issue that has come to our attention.

Finally, we need to discuss how HRSA's lack of regulatory authority limits the agency's ability to adequately oversee the program.

So the committee has been reviewing HRSA's oversight of the 340B program for pricing for 2 years and we plan to continue this work after this hearing. And as we move forward it is important not to overreact and create unnecessary red tape for providers who are truly using the program to benefit patients. And I have heard from hospitals in my district like those in Bend and even down on the south coast outside of my district just how important this program is to patients. While we do not want to overburden these safety net providers, we also need robust oversight over a program that has expanded this dramatically.

Just last month, the committee sent a letter to HRSA to gain more insight into the audits conducted in the 340B program and we want to extend our appreciation to HRSA for their timely production of information responsive to our requests. Thank you for doing that and we look forward to hearing about the steps that HRSA's taking to strengthen the program.

I also want to thank the Office of Inspector General at the U.S. Department of Health and Human Services and the GAO for your good work as well.

With that, I yield the balance of my time to the chairman of the Subcommittee on Health, Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman, and thank you, Mr. Chairman, for holding this hearing today.

As Chairman Walden pointed out, this program has saved billions of dollars for patients, ensuring that those in need could receive care and that the hospitals that provide that care can continue to support their communities.

But the program has challenges and audits by HRSA have found high levels of noncompliance among 340B-covered entities, raising questions as to who is currently overseeing the program and who should provide that oversight, going forward.

So I also want to thank our witnesses for being here today and discussing this very important program with us. This is a multifaceted problem.

The way forward isn't entirely clear but that is what this hearing is to sort out. So I am grateful we are having the hearing today and look forward for an opportunity to examine the 340B landscape, going forward.

And I yield back.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Mr. Chairman, for this hearing. This committee has really been ramping up its top-to-bottom oversight of many aspects of our health care system. The subcommittee's hearing on the 340B drug pricing program and the oversight role of the Health Resources and Services Administration, or HRSA, is part of this broader overview.

Since its creation by Congress in 1992, the 340B drug pricing program has provided life-saving medicines at reduced prices to certain safety-net health care providers. Indeed, this program has helped these providers known as "covered entities" stretch scarce federal dollars as far as possible to better serve uninsured and underinsured patients across the country. HRSA estimated that, in 2015, covered entities saved about \$6 billion on 340B drugs through their participation in the program.

For a variety of reasons, participation by hospitals in the 340B program has grown substantially in recent years. The number of unique hospital organizations participating in the program has nearly quadrupled from 2011 to 2016—increasing from 3,200 participating hospitals in 2011 to 12,148 in October 2016.

With this program growth, concerns have surfaced about HRSA's ability to adequately oversee the program. As the witnesses from the HHS Inspector General's office and GAO will discuss in detail today, HRSA's oversight of the program has improved in recent years through enhanced authority and resources, but program vulnerabilities still exist. Today, we will examine a number of important programmatic issues:

- First, we want to learn how HRSA's oversight efforts can best meet the challenge of 340B program growth. While HRSA has made improvements to its oversight efforts in recent years, HRSA's audit activity has remained at or below 200 annual audits of covered entities since 2012 despite the rapid growth of the program. That's one reason we are here today—to answer the question: how can HRSA improve its audits to better detect problems or somehow raise the annual number of audits?

- Next, we will focus on the problems already discovered and how HRSA can address them. HRSA's annual audits reveal a high level of noncompliance with program requirements by covered entities, including the potential for duplicate discounts and diversion of 340B drugs to ineligible patients.

- We will also want to find out how HRSA can be more transparent. Lack of transparency hinders HRSA's oversight capabilities. While the purpose of the program is to "stretch scarce resources as far as possible, reaching more eligible patients and providing more comprehensive services," neither the 340B statute nor HRSA guidance explains how 340B providers must use savings from the program.

- Finally, we will discuss how HRSA's lack of regulatory authority limits the agency's ability to adequately oversee the program.

The committee has been reviewing HRSA's oversight of the 340B drug pricing program for over two years, and plans to continue this work after the hearing. As we move forward, it's also important not to overreact and create unnecessary red tape for providers who are truly using the program to benefit patients. I've heard from hospitals in rural areas, like those in my district, that use 340B discounts to help beneficiaries in underserved parts of the country. While we do not want to overburden these safety-net providers, we also need robust oversight in the program to determine where these scarce federal dollars are going.

Just last month, the committee sent a letter to HRSA to gain more insight into the audits conducted into the 340B program, and we want to extend our appreciation to HRSA for their timely production of information responsive to our requests. We look forward today to hearing from HRSA about the steps that they have taken to strengthen the program and the challenges they face in their efforts to oversee the program.

I also want to thank the Office of Inspector General at the U.S. Department of Health and Human Services and the Government Accountability Office for being here to discuss their important work on this topic too. We look forward to hearing their recommendations on how to best promote program integrity and improve the program.

Mr. MURPHY. Gentleman yields.

I now recognize the ranking member of the full committee, Mr. Pallone, for an opening statement for 5 minutes.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

Twenty-five years ago, Congress passed bipartisan legislation establishing the 340B program. Since its inception, the 340B program has played a critical role in ensuring that low-income and vulnerable individuals have access to affordable health care.

The 340B program provides discounts on outpatient drugs that have allowed safety net providers to be able to expand access to essential health care services for vulnerable patients. This program has been vital for safety net providers like community health centers, inner city and rural hospitals, HIV clinics, and hemophilia treatment centers. And the 340B program has made the difference between patients getting the lifesaving health care services and drugs they need or going without.

The Congress created this program with the intention of helping covered entities expand their capacity to serve their patients. By purchasing drugs at a discounted rate, 340B providers are able to stretch scarce resources to provide more comprehensive health services. Resources provided through the 340B program directly augment patient care throughout the country. It continues to support the mission of safety net providers that serve low-income, uninsured, and under insured patients. And the 340 program is a critically important health care program and the Health Resources and Service Administration, or HRSA, should have the authority it needs to strengthen the integrity of the program.

GAO and OIG have identified weaknesses in the oversight of the program which can have negative consequences for both the participating providers and drug manufacturers. HRSA should appropriately improve program integrity while protecting the mission of the 340B program and be given the necessary resources to oversee the program.

Last Congress, this committee worked on a bipartisan basis to try to address the concerns from stakeholders on all sides of this issue in a balanced and measured fashion. Our goal was to strengthen and support the mission of 340B to provide health services to those most in need. Unfortunately, we were not successful. But I continue to believe and I think we can all agree here today that the mission of this program is sound and the continued emphasis on program integrity will make the 340B program stronger now and in the coming years.

I want to be clear, however, that while I was always happy to have a conversation about strengthening the 340B program, it would be disingenuous for anyone on this committee to say that this hearing today is in any way a hearing on rising drug prices. The 340B program is not the problem or the solution to rising drug prices and that is why I am so concerned about the Trump administration's recently proposed rule containing a provision that would slash reimbursements on Medicare Part B drugs to 340B hospitals under the guise that doing so would somehow address the rising cost of prescription drugs.

When Health and Human Services Secretary Price announced the proposed rule change, he claimed that this rule will somehow

make drugs more affordable. And I want to be clear—this rule would have zero impact on the actual price of prescription drugs and would decimate the support that 340B hospitals rely on to serve needy patients.

This proposal is nothing more than a deep cut to many of the hospitals that serve as the bedrock of our safety net, and committee Democrats have repeatedly asked that this committee begin to have a real conversation about drug prices and this is not it.

And again, I urge the chairman to hold the hearing on drug pricing so we can hear from all the stakeholders involved and so we can begin to develop real solutions that will begin to drive down the cost of prescription drugs. Until then, I remain dedicated to finding ways to strengthen the 340B program and ensure that it continues to fulfil its essential mission. And I am grateful to our witnesses for being here today to talk about some of the challenges the program faces as well as its successes and the important role it continues to play.

And I yield back. I yield the time remaining to the gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Great. Thank you, Mr. Pallone.

I just wanted to say that at a time when high and escalating drug prices are a top concern for all Americans, the 340B drug discount program is a real winner.

It is a very modest government initiative that has huge benefits and helps our disproportionate share hospitals and many community health centers and other clinics all across the country provide affordable prescriptions to folks that need it that may not have insurance, that are really struggling to get by and then that helps those hospitals and those clinics stretch the dollar and keep the burden off the taxpayer.

Doesn't mean that it is immune from oversight and that is important for our hearing today but 340B is a real godsend for so many families and health providers across the country.

Thank you, and I yield back.

Mr. MURPHY. Gentlewoman yields back.

So now I ask unanimous that the members' written opening statements be introduced into the record, and without objection the documents will be entered into the record.

I would now like to introduce our panel of federal witnesses for today's hearing.

First, we have Captain Krista Pedley, director of the Office of Pharmacy Affairs at the Health Resources and Services Administration. I just want to say you also got your pharmacy degree from the University of Pittsburgh. Fine school. Fine school.

Next is Ms. Erin Bliss, who serves as assistant inspector general in the Office of Inspector General within the Department of Health and Human Service. I think more of a Notre Dame person there, right?

And Ms. Debra Draper, but you have a doctorate degree so I am going to call you doctor today. Yes, she is the director of health care for the Government Accountability Office.

Thank you all for being here today and providing testimony. We look forward to a productive discussion of HRSA's oversight of 340B drug pricing program.

You are all aware that this committee is holding an investigative hearing and when doing so has the practice of taking testimony under oath. Do any of you have any objections to testifying under oath?

Seeing no objections, the chair then advises you that under the rules of the House and rules of the committee you are all entitled to be advised by counsel.

Do any of you desire to be advised by counsel during testimony today?

OK. Seeing no things on that then we will proceed with swearing you in. Please rise, raise your right hand. I'll swear you in.

[Witnesses were sworn.]

Seeing all answered in the affirmative, you are now under oath and subject to the penalties set for in Title 18 Section 1001 United State Code.

We ask you all to give a five-minute summary of your written statement. Please try and stick with the 5 minutes. I will tap the gavel when you are close to that.

Captain Pedley, you are recognized first. 5 minutes.

STATEMENTS OF CAPT. KRISTA M. PEDLEY, PHARMD, MS, DIRECTOR, OFFICE OF PHARMACY AFFAIRS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ERIN BLISS, ASSISTANT INSPECTOR GENERAL, OFFICE OF EVALUATION AND INSPECTIONS, OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DEBRA DRAPER, DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF CAPT. KRISTA M. PEDLEY, PHARMD, MS

Ms. PEDLEY. Good morning, Chairman Murphy, Ranking Member DeGette, and members of the subcommittee.

I appreciate the opportunity to appear before you today to discuss the 340B program. HRSA shares the subcommittee's commitment to ensuring program integrity and today I will discuss steps we have taken to implement key provisions and strengthen oversight including some of the current challenges in managing the program.

The 340B program was authorized in 1992 to stretch scarce federal resources by reducing the cost of covered outpatient drugs to 340B-eligible entities. Approximately 12,300 entities and 26,000 associated sites participate in addition to over 600 manufacturers. We appreciate the work of the Office of Inspector General and the Government Accountability Office to provide recommendations on strengthening safeguards which inform our activities across all HRSA programs. Within our statutory authority HRSA has worked to address the majority of GAO and OIG recommendations through systematic efforts to improve the program.

Two recommendations remain open from GAO's 2011 study which direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient. The OIG's 2005 and 2006 reports include open recommendations that HRSA develop a pricing system to improve oversight and allow entities to secure pricing data.

Since 1992, HRSA has administratively established many requirements of the program for a series of guidance documents published in the Federal Register, typically after public comment.

In 2014, HRSA planned to issue a proposed omnibus regulation. However, that same year the U.S. District Court for the District of Columbia invalidated a 2013 final rule on a provision related to orphan drugs. HRSA then withdrew the proposed omnibus regulation from the Office of Management and Budget review. HRSA has prioritized rulemaking in areas in which the D.C. circuit has clearly recognized our regulatory authority.

The agency finalized a rule in January 2017 on a calculation of ceiling prices and the imposition of civil monetary penalties for manufacturers which will become effective October 1, 2017. HRSA also proposed a rule in August 2016 on the dispute resolution process. All other program policy areas were addressed in an August 2015 proposed omnibus guidance and we are working on next steps to address these policy issues.

The president's fiscal year '18 proposed budget commits to developing a legislative proposal to improve 340B program integrity and ensure that the benefits derived from participation are used to benefit patients, especially the low-income and uninsured. Specific legislative authority to conduct rulemaking for all provisions in the 340B statute would be more effective for facilitating HRSA's oversight and management of the program. Specifically, regulatory authority would also allow HRSA to provide greater clarity and specificity of program requirements.

HRSA works to verify that both 340B entities and manufacturers are in compliance. Regarding covered entity program efforts, we conduct initial certification, annual recertification and program audits. We have completed over 800 covered entity audits since 2012, which encompass nearly 11,000 offsite facilities and 18,000 contract pharmacy locations. HRSA also reaudits a select number of entities with findings that resulted in repayment to manufacturers. HRSA posts on our website a summary of audit findings. The findings have varied from minor database corrections to findings of diversion.

Through findings and audits, HRSA develops educational tools and resources for all 340B stakeholders in order to improve program integrity. The statute specifies the types of entities eligible to participate but does not specify how a covered entity may provide or dispense such drugs to its patients.

HHS has issued guidance recognizing entity use of contract pharmacies to dispense 340B drugs. The majority, or 73 percent, of entities do not contract with pharmacies. HRSA guidance outlines compliance requirements for entities that utilize these contract pharmacies, which HRSA reviews as part of our audits. If a covered entity is not providing oversight of its contract pharmacy, the pharmacy arrangement is terminated from the program.

HRSA is also actively engaged in manufacture oversight and has the authority to conduct audits of manufacturers. HRSA has conducted seven audits of manufacturers in addition to developing regulations and guidance specific to manufacturer compliance. In accordance with the statute, HRSA is required to collect information

from manufacturers to verify the accuracy of 340B ceiling prices and then make those ceiling prices available to the covered entities.

HRSA appreciates the work of the OIG and GAO to help strengthen the program. We look forward to continuing our partnership with them as well as with Congress to strengthen program integrity and enforce program requirements as well as increase transparency on how entities use the program to benefit low-income and uninsured patients.

I appreciate the opportunity to testify today and look forward to your questions.

[The prepared statement of Capt. Krista M. Pedley follows:]



STATEMENT OF

CAPT KRISTA M. PEDLEY, PharmD, MS

DIRECTOR
OFFICE OF PHARMACY AFFAIRS
HEALTHCARE SYSTEMS BUREAU
HEALTH RESOURCES AND SERVICES ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
U.S. HOUSE OF REPRESENTATIVES

JULY 18, 2017

Good morning Chairman Murphy, Ranking Member DeGette and Members of the Subcommittee. My name is CAPT Krista Pedley and I am the Director of the Office of Pharmacy Affairs, within the Health Resources and Services Administration (HRSA) at the U.S. Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss the 340B Drug Pricing Program. HRSA shares the Subcommittee's commitment to ensuring the integrity of this program. I will discuss today the steps we have taken to implement key provisions and strengthen oversight of the Program, and some of the current challenges we face in managing the Program.

HRSA focuses on improving access to healthcare services for people who are geographically isolated or economically or medically vulnerable. HRSA strives to maximize every dollar and utilize continuous improvement to achieve the best outcomes for those we serve. To that end, program integrity is essential to all HRSA programs, including the 340B Program.

The 340B Drug Pricing Program

The 340B Program was authorized by the Veterans Health Care Act of 1992. Based on Congressional report language,¹ the 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities, known as "covered entities," in order to stretch scarce Federal resources. Some examples of covered entities include disproportionate share hospitals, Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and hemophilia treatment centers. Covered entities must apply to participate in the 340B Program and, once eligibility is verified by HRSA, the entities may begin purchasing drugs at the statutorily-defined ceiling price. Approximately 12,300 covered entities and 26,000 associated sites participate.

Manufacturers participating in Medicaid enter into an agreement with HHS under which they cannot charge covered entities a price that exceeds the 340B ceiling price. Over 600 manufacturers participate in the Program.

We appreciate the work done by the Department of Health and Human Services Office of Inspector General (OIG) and the Government Accountability Office (GAO) to highlight potential program integrity vulnerabilities and provide recommendations on strengthening safeguards. HRSA relies on these recommendations to inform our program improvement activities across all HRSA programs, including the 340B Program. Since 2011, GAO and OIG reviews of the 340B Program have resulted in eight recommendations. Two recommendations from GAO's 2011 study which direct HRSA to clarify hospital eligibility requirements and the definition of a 340B patient, remain open. The OIG's 2005 and 2006 reports recommended that HRSA develop a pricing system to improve the oversight of the 340B Program and to allow entities access to secure pricing data to ensure that they are charged at or below the 340B ceiling price.

Within our statutory authority, HRSA has worked to address the majority of these recommendations through systematic efforts to improve the 340B Program. We continue to

¹ The House Report accompanying the original 340B Program legislation states the following intent: "[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).

welcome feedback from our stakeholder community, Members of Congress, GAO, and OIG to help strengthen our program operations and oversight.

340B Program Oversight

Since 1992, HRSA has administratively established many requirements of the 340B Program through a series of guidance documents published in the *Federal Register*, typically after notice and comment. In the past few years, HRSA has been undertaking systematic efforts to improve the 340B Program, including proposing new regulations and issuing program guidance. Collectively, these rules and guidance are intended to strengthen the integrity of the 340B Program.

In 2014, HRSA planned to issue a proposed omnibus regulation for the 340B Program to establish additional policy to advance its oversight of covered entities and manufacturers. In May 2014, before HRSA was scheduled to issue the proposed omnibus regulation, the U.S. District Court for the District of Columbia² invalidated a 2013 final rule on a provision in the 340B statute related to orphan drugs. HRSA withdrew the proposed omnibus regulation from Office of Management and Budget (OMB) in order to reevaluate the proposed regulation in light of the court's ruling.

On August 12, 2016, HHS issued a notice of proposed rulemaking³ on the 340B ADR process. On January 5, 2017, HHS promulgated regulations in the *Federal Register*⁴ on the calculation of ceiling prices and the imposition of civil monetary penalties for manufacturers, which will become effective October 1, 2017.

In the absence of new regulation on certain issues, HRSA issued a proposed 340B Omnibus Guidance in August 2015.⁵ We are working to determine next steps to address these policy issues.

Budget Proposals

The President's FY 2018 Budget commits to developing a legislative proposal to improve 340B Program integrity and ensure that the benefits derived from participation in the program are used to benefit patients, especially low-income and uninsured populations. HRSA has prioritized rulemaking in areas in which the D.C. District Court has clearly recognized our regulatory authority. Specific legislative authority to conduct rulemaking for all provisions in the 340B statute would be more effective for facilitating HRSA's oversight over, and management of, the 340B Program. In addition, specific regulatory authority would allow HRSA to provide greater clarity and specificity to Program requirements.

² *PhRMA v. HHS*, 43 F. Supp. 3d 28 (D.D.C. 2014).

³ 81 FR 53381 (August 12, 2016).

⁴ 82 FR 1210 (January 5, 2017).

⁵ 80 FR 52300, (August 28, 2015).

340B Program Integrity

HRSA places the highest priority on the integrity of the 340B Program and has strengthened oversight of this program. We work to verify that both 340B covered entities and manufacturers are in compliance with 340B Program requirements. We have always worked to achieve program integrity within our authority to provide clarity in important program areas.

We conduct efforts such as initial certification (entity enrollment and validation), annual recertification, and program audits (on-site audit of 340B compliance). When an entity applies for participation in the program, HRSA staff review and validate the applicant's eligibility based on statutory requirements. In addition, through the annual recertification process, covered entities verify that all eligibility information is up to date and attest to compliance. We have been conducting annual recertification for all covered entities over the last several years. Since 2012, there have been steady improvements in recertification efforts by all covered entities in the 340B Program.

Fiscal year 2017 is our sixth year of covered entity audits. Random audits continue to be selected using a risk stratification methodology, so that entities with higher risk factors are more likely to be selected for audit. Targeted audits are also performed and may be triggered by reported violations or allegations.

The 340B covered entity audit process begins with a selected covered entity receiving an engagement letter explaining what to expect and how to prepare for the audit. HRSA auditors follow a strict protocol when conducting an audit. After the completion of the audit, the entity receives a preliminary report, and is granted one opportunity for "notice and hearing," by which it can submit a written disagreement addressing any or all of the audit findings. If the entity submits a disagreement, HRSA considers additional points raised, which may result in adjusted findings. The entity is then issued a Final Report. If findings were included in the final report, the entity would be required to submit to HRSA a Corrective Action Plan (CAP), which would include repayment to manufacturers for findings of diversion, duplicate discount, and/or violation of the Group Purchasing Organization prohibition.

To ensure the transparency of the audit process, HRSA posts a summary of final audit findings, including the name of the covered entity, on the Office of Pharmacy Affairs public website. As of June 26, 2017, we have completed 805 covered entity audits since we began auditing in 2012, which encompasses nearly 11,000 offsite outpatient/off-site facilities and nearly 18,000 contract pharmacy locations. In FY 2017, HRSA is on track to conduct an additional 200 covered entity audits. The findings of the audits have varied. Some findings were minor, requiring basic corrections in the 340B database (e.g., contact or address information was incorrect). Other audits found diversion, either through ineligible providers or ineligible sites. For audits with findings of a possible duplicate discount violation, the covered entity is required to work with the state to clarify and resolve the issue.

HRSA re-audits a select number of entities with findings that resulted in repayment to manufacturers. HRSA does not consider covered entities for re-audit until their audit is closed, which does not occur until after the CAP has been fully implemented. This policy is in place to

ensure the covered entity has time to fix the issue and has time to conduct repayment to manufacturers. Therefore, there is some time delay between the first audit and any subsequent re-audit. Through FY 2016, HRSA has re-audited 11 covered entities that were previously audited and had findings that resulted in repayment to manufacturers. HRSA plans to re-audit an additional 10 covered entities in FY 2017. To ensure we conduct a variety of audits in a given fiscal year, HRSA chooses its audits considering many factors, including but not limited to, entities that are eligible for a re-audit.

Through findings in the audits, HRSA develops educational tools and resources for all 340B stakeholders in order to improve overall program integrity.

In addition to covered entity oversight, we are actively engaged in manufacturer oversight. HRSA has the authority to conduct audits of manufacturers with program requirements. The audit process is the same as the process for covered entity audits as outlined above. As of July 1, 2017, HRSA conducted seven audits of manufacturers (one conducted with the assistance of the OIG). HRSA also ensures manufacturer compliance through development of regulations, guidance, and policy releases specific to manufacturer compliance. Additionally, HRSA verifies manufacturers that participate in Medicaid have signed a pharmaceutical pricing agreement, reviews all allegations brought to its attention, and requires refunds and credits when a covered entity is overcharged.

In accordance with the statute, HRSA is required to collect information from manufacturers to verify the accuracy of 340B ceiling prices, and then make ceiling prices available to covered entities.

Contract Pharmacy Use in the 340B Program

The statute specifies the types of entities eligible to participate in the 340B Program, but does not specify how a covered entity may provide or dispense such drugs to its patients. The diverse nature of eligible entity types has resulted in a variety of drug distribution systems. In 1996, HHS issued guidance recognizing covered entity use of contract pharmacy arrangements, which states had permitted, to dispense 340B drugs. The majority (73 percent) of covered entities do not contract with pharmacies. Of the 27 percent of covered entity organizations utilizing contract pharmacy arrangements, community health centers represent the largest users of contract pharmacy arrangements, with 73 percent of community health centers utilizing one or more contract pharmacies.

HRSA issued revised guidance in 2010 to further outline compliance requirements for covered entities that utilize contract pharmacies to dispense 340B drugs to their patients and to permit covered entities to utilize more than one contract pharmacy. The guidance states that covered entities are responsible for compliance of the contract pharmacies, and they must ensure against diversion and duplicate discounts, maintain auditable records, and meet all other program requirements. HRSA expects entities to conduct annual audits of their contract pharmacies in order to conduct sufficient oversight. If a covered entity is found to not be providing adequate oversight, the contract pharmacy arrangement is terminated from the 340B Program.

HRSA conducts audits of covered entities and their contract pharmacy arrangements and has included in the criteria for risk-based audits the number of contract pharmacy arrangements a covered entity utilizes. HRSA verifies the existence of a contract between a covered entity and contract pharmacy during its audits of 340B covered entities. Entities must demonstrate that they have mechanisms in place to prevent diversion and duplicate discounts. During audits, HRSA also reviews a sample of the records of 340B drugs dispensed at the contract pharmacy and reviews contract pharmacy compliance. During the annual recertification process, covered entities that have arrangements with contract pharmacies must attest that the arrangement is in compliance with all requirements set forth by the 340B Program. If an arrangement is found to be out of compliance with 340B Program requirements, HRSA may terminate the contract pharmacy arrangement from the 340B database so that manufacturers no longer ship 340B drugs to them.

Conclusion

HRSA appreciates the work of OIG and GAO to help strengthen the Program. We look forward to continuing our partnership with them as well as with Congress to strengthen program integrity and enforce program requirements, as well as increase transparency on how covered entities use the program to benefit low-income and uninsured patients.

Mr. MURPHY. Thank you.

Ms. Bliss, you are recognized for 5 minutes.

STATEMENT OF ERIN BLISS

Ms. BLISS. Good morning, Chairman Murphy, Ranking Member DeGette, and other distinguished members of the subcommittee. I am pleased to join you today to discuss ways to protect the integrity of the 340B drug discount program.

OIG has found that HRSA has strengthened its oversight of the 340B program over the years. However, more needs to be done. Some longstanding and fundamental challenges persist and they impede effective program oversight and operations. OIG recommends two key improvements to 340B program integrity and oversight: One, increase transparency to allow for payment accuracy; and two, clarify rules to ensure that the program operates as intended. I will explain both of these.

With respect to transparency, OIG recommends that HRSA shares ceiling prices with 340B providers and states. For providers, this will allow them to ensure that they are not overcharged by drug manufacturers. Currently, 340B providers cannot verify that they actually receive the required discount. Congress has given HRSA authority to do so and HRSA is working on it. Sharing ceiling prices with states will allow them to ensure that Medicaid is not overpaying for 340B drugs. Making this happen may require new authority from Congress. States also need transparency as to which Medicaid claims represent 340B drugs. Even when states can determine how much they should be paying for these drugs, they still may not know which claims to reimburse at that price. This transparency is also essential for states to correctly claim Medicaid rebates from drug manufacturers. Without it, states put manufacturers at risk for paying more rebates than they should by inappropriately including 340B drugs. At the same time, states risk forgoing rebates to which they are entitled by inappropriately excluding non-340B drugs. OIG recommends that HRSA work with the Centers for Medicare and Medicaid Services to help states accurately identify 340B claims.

The second key improvement is to clarify 340B program rules. For one, HRSA's guidance addresses patient eligibility but leaves room for interpretation as to which of a patient's prescription might be eligible in a retail pharmacy setting. In these retail settings we found that providers in fact are making different determinations about which prescriptions are eligible for the 340B price.

Let me illustrate with an example. Let us imagine a doctor sees a patient at a 340B community health center. Later, that same doctor sees the same patient at her private practice. If the doctor prescribes a drug to that patient at the private practice, is that prescription eligible for the 340B price? One provider in our study said yes and another said no, and another said it depends. So who is right? We couldn't tell, based on the current guidance, and so we recommend that HRSA more clearly define this.

Furthermore, guidance does not address how to handle uninsured patients. In our review of retail pharmacies, we found that uninsured 340B patients sometimes received discounted prices but sometimes they paid full price for 340B drugs. In other words, un-

insured patients are not always receiving the benefit of the 340B discount on their prescriptions. We recommend that HRSA address whether providers must offer discounted prices to uninsured patients.

In closing, lack of transparency and clarity make it harder to ensure integrity and harder to determine how well the program is working. If HRSA needs new authorities to make these key improvements, we encourage Congress to consider statutory changes as appropriate to support increased transparency and better clarity.

OIG appreciates and shares your interest in improving program integrity and effectiveness for the 340B program. I will look forward to answering your questions. Thank you.

[The prepared statement of Erin Bliss follows:]



**Testimony Before the United States House of Representatives
Committee on Energy and Commerce:
Subcommittee on Oversight and Investigations**

Examining HRSA's Oversight of the 340B Drug Pricing Program

Testimony of:

**Erin Bliss
Assistant Inspector General for Evaluation and Inspections
Office of Inspector General
U.S. Department of Health and Human Services**

July 18, 2017

10:15 a.m.

Location: 2322 Rayburn House Office Building

Testimony of:

Erin Bliss

Assistant Inspector General for Evaluation and Inspections
Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee. I am Erin Bliss, Assistant Inspector General for Evaluation and Inspections for the Office of Inspector General (OIG), U.S. Department of Health and Human Services. I appreciate the opportunity to appear before you to discuss ways to protect the integrity of the 340B Drug Pricing Program (340B program).

OIG oversees the Health Resources and Services Administration's (HRSA) operation of the 340B program. OIG reviews have explored various aspects of the 340B program, identified potential vulnerabilities, and offered several recommendations to promote program integrity. Some of the weaknesses we have identified have been addressed through legislation or by HRSA directly. However, some long-standing, fundamental vulnerabilities persist, impeding effective program oversight and operations. Specifically, OIG work has identified: 1) a lack of transparency that prevents accurate payments by 340B providers, State Medicaid programs, and pharmaceutical manufacturers; and 2) a lack of clarity regarding program rules that creates uncertainty and results in uneven program implementation and limited accountability. HRSA has taken some steps toward addressing these concerns, but it has not fully addressed either. My testimony today focuses on the two key improvements OIG recommends to support effective oversight and strengthen the integrity of the 340B program.

OIG Recommends Key Improvements to 340B Program Integrity and Oversight:

- increase transparency to allow payment accuracy, and
- clarify rules to ensure that the program operates as intended.

The 340B Program Requires Drug Manufacturers to Sell Products at Discounted Prices to Certain Safety-Net Health Care Providers

In 1992, Congress established the 340B program to generate savings for certain safety-net health care providers by allowing them to purchase outpatient drugs at discounted prices.¹ These savings could then be used to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."² HRSA manages the 340B

¹ Section 340B of the Public Health Service Act, 42 U.S.C. § 256b

² H.R. Rept. No. 102-384 (Part 2), at 12 (1992) (Conf. Rept.).

program and estimated that the savings to 340B providers attributable to the program in 2015 was \$6 billion.³

Pursuant to the Public Health Service Act, drug manufacturers sign a Pharmaceutical Pricing Agreement stipulating that they will charge certain eligible health care providers (340B providers) at or below specified maximum prices, known as ceiling prices. The manufacturers calculate 340B ceiling prices each quarter by applying a statutorily defined formula to confidential drug pricing data. The 340B providers benefiting from these discounted prices include such safety-net providers as community health centers and hospitals that serve a disproportionate number of low-income patients. In 2010, the Affordable Care Act expanded the types of providers eligible to participate in the 340B program to include children's hospitals, critical access hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals. As of October 1, 2016, the 340B program included 12,148 providers and 25,348 associated sites, for a total 37,496 registered sites.⁴

The 340B program also intersects with State Medicaid programs in important ways. One way relates to how State Medicaid programs reimburse 340B providers for drugs provided to Medicaid beneficiaries. As of February 2016, the Centers for Medicare & Medicaid Services (CMS) requires State Medicaid agencies to reimburse providers for 340B-purchased drugs at amounts that do not exceed the 340B ceiling price.⁵ Another way relates to how States claim Medicaid rebates from drug manufacturers. In general, States are entitled to statutorily defined rebates from manufacturers for covered outpatient drugs. However, "duplicate discounts" – which occur when drug manufacturers pay rebates to State Medicaid agencies on drugs that they sold at the already discounted 340B price – are prohibited by law.⁶

HRSA Has Strengthened Its Oversight of the 340B Program Over the Years, But Some Key Challenges Persist

Across numerous OIG reviews of the 340B program, our work has identified program integrity vulnerabilities, many of which have been addressed, but others continue to be concerns.⁷ Our initial work, released in the early 2000s, found deficiencies in HRSA's oversight of the program. These deficiencies included inaccurate information regarding which providers were eligible for discounted prices and a lack of systematic monitoring to ensure that drug manufacturers were charging 340B providers the correct prices. Systemic monitoring by HRSA was critical, at the time, because confidentiality protections prevented HRSA from sharing the ceiling prices with

³ 82 Fed. Reg. 1210, 1227 (January 5, 2017).

⁴ HRSA, *Fiscal Year 2018 Justification of Estimates for Appropriations Committees*, p. 245.

⁵ 81 Fed. Reg. 5170 (February 1, 2016); 42 C.F.R. § 447.518(a)(2).

⁶ 42 U.S.C. § 256b(a)(5)(A)(i); 42 U.S.C. § 1396r-8(j)(1).

⁷ OIG has issued seven evaluations of the 340B program: (1) *Deficiencies in the 340B Drug Pricing Program's Database*, OEI-05-02-00071, June 2004; (2) *Deficiencies in Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, October 2005; (3) *Review of 340B Prices*, OEI-05-02-00073, July 2006; (4) *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011; (5) *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014; (6) *Medicaid Drug Rebate Dispute Resolution Could Be Improved*, OEI-05-11-00580, August 2014; and (7) *State Efforts to Exclude 340B Drugs From Medicaid Managed Care Rebates*, OEI-05-14-00430, June 2016.

340B providers. This lack of transparency left 340B providers unable to determine whether they were paying accurate amounts to drug manufacturers. Further, HRSA lacked the necessary enforcement tools for holding manufacturers accountable.

In recent years, HRSA has taken steps to improve oversight of the 340B program and been granted additional oversight authorities. For example, HRSA has issued several technical assistance resources to educate manufacturers and 340B providers to facilitate compliance. In one case, HRSA created a training webinar for 340B providers to help them ensure compliance with program requirements to prevent duplicate discounts when working with Medicaid patients. During this same time, HRSA was authorized in legislation to share the discounted ceiling prices with 340B providers. HRSA was also granted new enforcement tools that it has been using. For example, HRSA now conducts audits of selected manufacturers and 340B providers.

Some of HRSA's efforts to strengthen 340B program integrity through regulations were unsuccessful. HRSA proposed an omnibus 340B regulation, but withdrew it prior to publication after a Federal court ruling established limits on HRSA's rulemaking authority for the 340B program. In 2015, HRSA instead issued proposed omnibus 340B guidance.⁸ However, this guidance was withdrawn in January 2017. HRSA did not provide a reason for withdrawing the guidance.

Despite progress in addressing some program vulnerabilities, the steps HRSA has taken have not fully addressed the long-standing challenges identified by OIG. As such, OIG continues to recommend improving the 340B program by: (1) increasing transparency, and (2) clarifying program rules. HRSA, CMS, and Congress each have roles in advancing these improvements. These broad recommendations are explored in detail below.

OIG RECOMMENDS: Increasing Transparency to Allow Payment Accuracy

Transparency is needed to support payment accuracy in three ways. First, 340B providers need to know the 340B ceiling prices to determine whether they are paying the accurate price. Second, State Medicaid programs need to know the 340B ceiling price, as well as which Medicaid claims are for 340B-purchased drugs, to determine whether they are paying 340B providers accurately. Third, State Medicaid programs need to know which Medicaid claims are for 340B-purchased drugs to ensure that Medicaid programs receive all of the drug rebates to which they are entitled and manufacturers do not provide duplicate discounts. However, the lack of transparency regarding 340B prices and claims hampers payment accuracy in all of these transactions.

The lack of transparency in ceiling prices impedes 340B providers and Medicaid programs from ensuring that they have paid the correct amount for 340B-purchased drugs.

Although Congress authorized HRSA to share confidential ceiling prices with 340B providers in 2010, HRSA has not yet done so. HRSA has begun to develop a secure system for sharing

⁸ 80 Fed. Reg. 52300 (August 28, 2015)

ceiling prices with 340B providers. HRSA plans for the system to be a single point of reference to calculate, verify, and display 340B ceiling prices. According to these plans, 340B providers will be able to access the system to view 340B ceiling prices and verify that they are paying at or below the posted 340B ceiling price. Manufacturers will also be able to upload their quarterly pricing data and validate their prices with the HRSA-verified 340B ceiling price. HRSA identifies this initiative as an ongoing priority for fiscal year 2018.⁹ However, until the system is operational, 340B providers cannot ensure that they are paying the right amount.

The 2010 legislation addressed access to ceiling prices for 340B providers, but it did not address access for State Medicaid agencies. Lack of access to 340B ceiling prices can prevent State Medicaid agencies from effectively enforcing Medicaid payment policies for 340B-purchased drugs. OIG found that without access to 340B ceiling prices, States are unable to implement automated, prepayment edits to enforce these policies. Instead, some States conduct labor-intensive and potentially costly audits and post-payment reviews in an attempt to ensure that they have paid 340B providers correctly for 340B-purchased drugs. HRSA concurred with OIG's recommendation to share ceiling prices with States but may need additional statutory authority to do so.¹⁰

The lack of transparency in Medicaid claims for 340B-purchased drugs hinders States' efforts to pay providers correctly and to claim correct Medicaid rebates from manufacturers.

States also need transparency into which Medicaid claims represent 340B-purchased drugs to ensure that they make payments in accordance with their payment policies. Even if States can determine *how much* they should be paying 340B providers for 340B-purchased drugs, they still may not know *which claims* to reimburse at that rate.

Likewise, knowing which Medicaid claims represent 340B-purchased drugs is essential for States to correctly claim rebates from manufacturers. If States cannot accurately identify which Medicaid claims involve 340B-purchased drugs, two types of problems may result. One, States may inappropriately *include* claims for 340B-purchased drugs in rebate invoices sent to manufacturers, potentially causing duplicate discount situations. Two, States may inappropriately *exclude* claims for non-340B-purchased drugs and forgo rebates to which they are entitled. In addition, without reliable methods for identifying claims for 340B-purchased drugs, States may be more likely to have rebate disputes with drug manufacturers, which would require additional resources to resolve and may impede or delay rebate payments.

HRSA maintains a tool, the Medicaid Exclusion File, to assist States in identifying providers who have chosen to dispense 340B-purchased drugs to Medicaid patients in the fee-for-service program. OIG found that in 2015, States typically used HRSA's Medicaid Exclusion File to identify and exclude 340B drug claims for the purpose of collecting rebates.¹¹ However, we found that this provider-level approach may not accurately identify all individual 340B drug

⁹ HRSA, *Fiscal Year 2018 Justification of Estimates for Appropriations Committees*, p. 245.

¹⁰ OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011.

¹¹ OIG, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430, June 2016.

claims, creating a risk of duplicate discounts and forgone rebates. We found that methods that operate at the claim level can improve accuracy in identifying 340B drug claims and thereby help prevent duplicate discounts and improve collection of rebates. Identifying and excluding 340B claims paid by Medicaid managed care organizations involves additional complications, and claims-level transparency would help address these challenges, too.

To increase transparency, OIG recommended that CMS require States to use claim-level methods to identify 340B claims. CMS did not concur with OIG's recommendation to require the use of claim-level methods to identify 340B claims, stating that it agreed with the importance of claim-level methods but that the statute "does not contemplate" such a requirement. To the extent that CMS determines it does not have sufficient statutory authority to implement such a requirement, additional action from Congress may be needed.

OIG RECOMMENDS: Clarifying Rules to Ensure that the 340B Program Operates as Intended

OIG has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements. Contract pharmacies are external pharmacies (often retail pharmacies) that partner with 340B providers to dispense 340B-purchased drugs to the providers' patients, and their prevalence is on the rise. These pharmacies typically dispense both 340B-purchased drugs on behalf of 340B providers, as well as non-340B drugs. The operations of contract pharmacies are often quite complex, and this complexity has important consequences—variation in eligibility determinations across different 340B providers and inconsistencies in whether uninsured patients benefit directly from the 340B program. As such, OIG recommends that HRSA clarify rules to address these ambiguities and inconsistencies.

HRSA initiated steps to address OIG's concerns by proposing updates and clarifications that address the patient definition, contract pharmacy arrangements, and other program integrity provisions in its 2015 proposed omnibus 340B guidance. However, HRSA never finalized that proposed guidance. As such, these issues remain unaddressed. To address these issues through rulemaking, HRSA may need additional statutory authority.

HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements.

340B providers are prohibited by law from dispensing 340B-purchased drugs to anyone who is not their patient.¹² However, the law does not further define what constitutes a "patient." HRSA's official definition of patient eligibility comes from guidance issued before 340B providers were permitted to contract with networks of retail pharmacies. That guidance specifies that an individual is an eligible patient only if he or she has an established relationship with the 340B provider, he or she receives health care services from the 340B

¹² 42 U.S.C. § 256b(a)(5)(B).

provider, and those services are consistent with the service or range of services for which Federal funding is being granted.^{13, 14}

Dispensing a 340B-purchased drug to an ineligible patient, which is prohibited by law, is referred to as “diversion.” Thus, appropriately determining patient eligibility for 340B-purchased drugs is critical to preventing diversion.

Although the law and HRSA guidance focus on 340B eligibility at the patient level, operationally, contract pharmacies determine eligibility at the prescription level. Retail contract pharmacies often have no way to distinguish a 340B patient from any other customer filling a prescription at their stores. To address this reality, many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory. Only later, after dispensing a drug, do these contract pharmacies determine which prescriptions were given to 340B-eligible patients. They then order the appropriate quantity of drugs at 340B prices to replenish their inventory.

To identify which prescriptions were given to 340B-eligible patients, contract pharmacies often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In its 2014 report, OIG found wide variation in these eligibility determinations. Different determinations of 340B eligibility appear to stem from the application of the patient definition by 340B providers and their contract pharmacies to a wide variety of prescription-level scenarios.¹⁵ Depending on the interpretation of HRSA’s patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.

HRSA’s current guidance on patient definition does not account for many of the 340B eligibility decisions that arise in contract pharmacy arrangements. The following example illustrates how contract pharmacy operations have led to different determinations of 340B eligibility in the absence of a clearer patient definition:

Scenario: Nonexclusive physician

A physician practices part time at a 340B provider, but also has a private practice. The physician first sees an individual at the 340B provider. Separately, the physician sees the same individual at his private practice and writes a prescription for that person. The individual fills the prescription at the 340B provider contract pharmacy.

¹³ Disproportionate share hospitals are exempt from the requirement that services be consistent with the service or range of services for which Federal funding is being granted.

¹⁴ 61 Fed. Reg. 55156, 55157-8 (October 24, 1996).

¹⁵ OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014.

Whether contract pharmacies determine the prescription in this scenario to be 340B-eligible depends on how they match their dispensing data to information from the 340B provider. One 340B provider in OIG's report noted that it would automatically categorize the prescription in this scenario as 340B-eligible because it uses a list of all prescribers working at the 340B provider to identify 340B-eligible prescriptions. Because the physician in this scenario would be on the prescriber list, the prescription would be categorized as 340B-eligible, even though it was written at the physician's private practice (i.e., it originated outside the 340B provider).

Another 340B provider in OIG's report noted that it would *not* categorize the prescription in this scenario as 340B-eligible because, although the 340B provider's contract pharmacy also uses a prescriber list to identify 340B-eligible prescriptions, it limits the prescriber list only to those prescribers who work exclusively for the 340B provider. Because the physician in this scenario would not be on the prescriber list (as he does not work exclusively for the 340B provider), the prescription would not be categorized as 340B-eligible.

In its 2015 proposed omnibus guidance, HRSA proposed an update to the patient definition that could have addressed this scenario. The guidance proposed a six-part patient definition, to be applied on a prescription-by-prescription basis, that would have deemed prescriptions to be 340B-eligible only if they resulted from a service (e.g., a physician consultation) provided by the covered entity. However, HRSA has not issued final guidance on the patient definition.

Neither the 340B statute nor HRSA guidance addresses whether 340B providers must offer the discounted price to uninsured patients.

Despite the 340B program's goal of increasing access and providing more comprehensive care, neither the 340B statute nor HRSA guidance speaks to how 340B providers must use savings from the program—nor do they stipulate that the discounted 340B price must be passed on to uninsured patients. Given this discretion, some 340B providers have chosen to institute extra measures to ensure that uninsured patients benefit through lower drug costs when filling prescriptions at contract pharmacies. If they do not, uninsured patients can pay full price for drugs filled at contract pharmacies and thus not directly benefit from the 340B discount on their prescriptions. Guidance on how the program should apply to uninsured patients in these scenarios should be clarified to ensure that patients are treated consistently across 340B providers and that operations align with the program's intent.

In OIG's 2014 report on 340B contract pharmacy arrangements, we found that several 340B providers did not offer the discounted price to their uninsured patients at contract pharmacies.¹⁶ These 340B providers' contract pharmacy arrangements would have required additional processes to identify uninsured patients as 340B-eligible because, as previously noted, many contract pharmacies do not know which patients are from the 340B providers when they come to the pharmacy. Not knowing whether the patient is 340B-eligible may not have a financial impact on insured patients, because their costs are often determined by standard copayments stipulated in their insurance plans. OIG did not assess the specific consequences for insured

¹⁶ OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014.

patients in its report. For uninsured patients, not knowing whether they are 340B-eligible means that they may be charged the full price for their drugs. Contract pharmacies may later identify uninsured patients' prescriptions as 340B-eligible, but those patients will have paid full price.

Conclusion and Specific OIG Recommendations

We appreciate the Subcommittee's interest in these important issues. We also appreciate the progress that HRSA has made to improve its oversight of the 340B program. However, we continue to urge HRSA, in coordination with CMS, to improve transparency of 340B pricing information for 340B providers and State Medicaid agencies and to improve transparency of claims for 340B-purchased drugs. Specifically, we recommend that:

- HRSA fully implement its authority to share ceiling prices with 340B providers;
- HRSA work with CMS, and with Congress to obtain any needed authority, to share ceiling prices with State Medicaid agencies; and
- CMS require Medicaid programs to use claims-level methods to identify claims for 340B-purchased drugs and that HRSA update its related guidance.

Clarifying 340B program rules in a complex and evolving health care delivery system is also essential. Without clear rules, HRSA oversight is compromised, program implementation and outcomes vary, and vulnerabilities in 340B program integrity persist. OIG recommends that HRSA:

- clarify the definition of eligible patient; and
- address whether 340B providers must offer discounted 340B prices to uninsured patients.

To the extent that HRSA determines it does not have sufficient statutory authority to carry out these recommendations, we encourage Congress to consider statutory changes to support increased clarity in program goals and requirements and more effective oversight.

Thank you for the opportunity to testify on ways to improve oversight of the 340B program. OIG will continue to work with HRSA, CMS, and Congress to protect the integrity of this program and help ensure that it is efficiently and effectively meeting its intended goals.

Mr. MURPHY. Thank you, Ms. Bliss.
Dr. Draper, you are recognized for 5 minutes.

STATEMENT OF DEBRA A. DRAPER

Ms. DRAPER. Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, thank you for the opportunity to be here today to discuss the 340B program including issues concerning its oversight.

The 340B program was created by statute in 1992 and is administered by HRSA. According to HRSA, the intent of the program is to enable participating entities, also known as covered entities, to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services. Participation is voluntary but there are strong incentives to do so. For covered entities such as certain hospitals and federally-qualified health centers, substantial cost savings or revenue on outpatient drugs can be obtained through participation in the program.

For drug manufacturers, participation is required to receive Medicaid reimbursement. Since the 340B program first became operational in 1993, it has experienced exponential growth in the number of covered entities. In 1993, the program had approximately 400 covered entities and by 2017 there were more than 12,000 representing approximately 38,000 covered sites.

The 340B program has also seen exponential growth in the number of contract pharmacies particularly since 2010. Prior to March 2010, only one contract pharmacy was allowed for covered entities without an in-house pharmacy. In March 2010, HRSA lifted that restriction and as a result, the number of contract pharmacies increased from about 1,300 in 2010 to nearly 19,000 in 2017, encompassing more than 46,000 arrangements.

In 2011, we reported that HRSA's oversight of the 340B program was inadequate to provide reasonable assurance that participants were in compliance with program requirements. As a result of the identified weaknesses, we made four recommendations. One recommendation was for HRSA to conduct audits of covered entities to ensure compliance with program requirements. This recommendation was a result of our findings that HRSA primarily relied on participants to self-police and ensure their own compliance.

In fiscal year 2012, HRSA initiated audits of covered entities and now conducts 200 audits per year. While we are pleased that HRSA is conducting these audits, 200 per year may be insufficient, given the continued escalation and the number of covered entities. A second recommendation was for HRSA to clarify the guidance for cases in which the distribution of drugs is restricted including required reviews of manufacture plans to ensure that drugs are equitably distributed to all entities regardless of 340B, program participation. This recommendation was the result of our finding that in cases such as when the drug is inherently limited, manufacturers may have restricted distribution but the manner in which they did so was not always clear.

HRSA issued updated guidance in fiscal year 2012, which addressed their recommendation. The remaining two recommendations were for HRSA to issue more specific program guidance on the definition of a patient eligible to receive discounted drugs

through the program and the criteria that hospitals must meet to be eligible to participate. These recommendations were the result of our findings that the lack of specificity in the guidance could be interpreted in ways that were inconsistent with the programs intent. This was particularly troubling given that the 340B program has been increasingly used in settings such as hospitals where the risk of diverting 340B drugs to ineligible patients is greater because these settings are more likely to serve such patients.

HRSA has attempted but not succeeded in addressing these two open recommendations. In 2014, it developed a comprehensive 340B program regulation but a court ruling found that HRSA's rulemaking authority for the program was limited to specified areas. In 2015, it issued proposed guidance but withdrew plans to finalize it earlier this year following the administration's directive for agencies to withdraw pending regulations and guidance.

In summary, HRSA has undertaken efforts to improve oversight of the 340B program. However, there are a number of critical issues that remain unresolved including whether the intent of the program, which was established nearly 25 years ago, is still relevant today, given the vastly changed healthcare landscape and 340B program environment. Continued lack of specificity and program guidance, most notably the definition of a patient and hospital eligibility criteria.

Until these issues are resolved there will continue to be concerns about the integrity of the 340B program and HRSA's ability to provide effective oversight.

Mr. Chairman, this concludes my opening remarks. I am happy to answer any questions.

[The prepared statement of Debra A. Draper follows:]

United States Government Accountability Office



Testimony

Before the Subcommittee on Oversight
and Investigations, Committee on
Energy and Commerce, House of
Representatives

For Release on Delivery
Expected at 10:15 a.m. ET
Tuesday, July 18, 2017

**DRUG DISCOUNT
PROGRAM**

**Update on Agency Efforts
to Improve 340B Program
Oversight**

Statement of Debra A. Draper
Director, Health Care

GAO Highlights

Highlights of GAO-17-749T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

According to HRSA, the purpose of the 340B Program, which was created in 1992, is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services. Covered entities can provide 340B drugs to patients regardless of income or insurance status and generate revenue by receiving reimbursement from patients' insurance. The program does not specify how this revenue is to be used or whether discounts are to be passed on to patients. The number of participating covered entity sites—currently about 38,000—has almost doubled in the past 5 years and the number of contract pharmacies increased from about 1,300 in 2010 to around 18,700 in 2017. In recent years, questions have been raised regarding oversight of the 340B Program, particularly given the program's growth over time.

In September 2011, GAO identified inadequacies in HRSA's oversight of the 340B program and made recommendations for improvement. This statement describes (1) HRSA actions in response to GAO recommendations to improve its program oversight, and (2) ongoing GAO work regarding the 340B program and HRSA oversight.

For this statement, GAO obtained information and documentation from HRSA officials about any significant program updates and steps they have taken to implement the 2011 GAO recommendations. More detailed information on the objectives, scope, and methodology can be found in GAO's September 2011 report.

View GAO-17-749T. For more information, contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov.

July 18, 2017

DRUG DISCOUNT PROGRAM

Update on Agency Efforts to Improve 340B Program Oversight

What GAO Found

The 340B Drug Pricing Program requires drug manufacturers to sell outpatient drugs at discounted prices to covered entities—eligible clinics, hospitals, and others—to have their drugs covered by Medicaid. Covered entities are only allowed to provide 340B drugs to certain eligible patients. Entities dispense 340B drugs through in-house pharmacies or contract pharmacies, which are outside pharmacies entities contract with to dispense drugs on their behalf. The number of contract pharmacies has increased significantly in recent years.

In its September 2011 report, GAO found that the Health Resources and Services Administration's (HRSA) oversight of the 340B program was inadequate to ensure compliance with program rules, and GAO recommended actions that HRSA should take to improve program integrity, particularly given significant growth in the program in recent years. HRSA has taken steps to address two of GAO's four recommendations:

- **HRSA initiated audits of covered entities.** GAO found that HRSA's oversight of the 340B Program was weak because it primarily relied on covered entities and manufacturers to ensure their own compliance with program requirements and HRSA engaged in few oversight activities. GAO recommended that HRSA conduct audits of covered entities and in fiscal year 2012, HRSA implemented a systematic approach to conducting annual audits of covered entities. HRSA now conducts 200 audits a year, which have identified instances of non-compliance with program requirements, including the dispensing of drugs to ineligible patients.
- **HRSA clarified guidance for manufacturers.** GAO found a lack of specificity in guidance for manufacturers for handling cases in which distribution of drugs is restricted, such as when there is a shortage in drug supply. GAO recommended that HRSA refine its guidance. In May 2012, HRSA clarified its policy for when manufacturers restricted distribution of a drug and provided additional detail on the type of information manufacturers should include in their restricted distribution plans.
- **HRSA has not clarified guidance on two issues.** GAO also found that HRSA guidance on (1) the definition of an eligible patient and (2) hospital eligibility criteria for program participation lacked specificity and recommended that HRSA clarify its guidance. HRSA agreed that clearer guidance was necessary and, in 2015, released proposed guidance that addressed both issues. However, earlier this year, the agency withdrew that guidance in accordance with recent directives to freeze, withdraw, or postpone pending federal guidance.

Given particular concerns that the significant escalation in the number of contract pharmacies poses a potential risk to the integrity of the 340B Program, GAO was asked to examine this issue and expects to issue a future report, in which it plans to address the extent to which covered entities use contract pharmacies; financial arrangements between covered entities and pharmacies; the provision of discounts on drugs dispensed by contract pharmacies to low-income, uninsured patients; and how covered entities and HRSA ensure compliance with 340B program requirements at contract pharmacies.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee:

I am pleased to be here today as you examine the 340B Drug Pricing Program (340B Program), including issues concerning its oversight. The program, created in 1992 and named for the statutory provision authorizing it in the Public Health Service Act (PHSA), requires drug manufacturers to sell outpatient drugs at discounted prices to eligible clinics, hospitals, and other entities—commonly referred to as covered entities—in order to have their drugs covered by Medicaid.¹ According to the Health Resources and Services Administration (HRSA), the agency within the Department of Health and Human Services (HHS) responsible for administering and overseeing the 340B Program, the purpose of the program is to enable covered entities to stretch scarce federal resources to reach more eligible patients, and provide more comprehensive services.² In recent years, questions have been raised regarding HRSA's oversight of the 340B Program, particularly given growth in the program over time. According to HRSA, as of January 2017, covered entities had more than 38,000 sites participating in the 340B Program—almost double the number reported just 5 years earlier.³

Participation in the 340B Program is voluntary for both covered entities and drug manufacturers, but there are strong incentives to participate:

- Covered entities can realize substantial savings through 340B price discounts—an estimated 20 to 50 percent of the cost of the drugs, according to HRSA. In addition, covered entities can generate 340B revenue. For example, they can purchase drugs at 340B prices for all eligible patients regardless of the patients' income or insurance status and generate revenue, such as by receiving reimbursement from a patient's insurance that may exceed the 340B price paid for the drugs. The 340B Program does not dictate how covered entities should use

¹42 U.S.C. § 256b.

²HRSA bases this view on language in a House Energy and Commerce Committee Report pertaining to language similar to what eventually became section 340B of the PHSA. See H. Rep. No. 102-384, Pt. 2, at 12 (1992) (discussing bill to amend the Social Security Act). See also Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the PHSA).

³Data represent both unique covered entities and all their eligible sites, such as satellite clinics. According to HRSA, there were 12,340 unique organizations participating in the program as of January 1, 2017.

this revenue or require that discounts on the drugs be passed on to patients.

- Incentives for participation by drug manufacturers also are strong because they must participate in the 340B Program to receive Medicaid reimbursement for their drugs. According to HRSA, most manufacturers that produce outpatient drugs have participated in the program since its inception.

HRSA also requires program participants to meet certain conditions set forth both in law and agency guidance. For example, covered entities are prohibited from diverting 340B drugs—that is, transferring 340B drugs to individuals who are not eligible patients of the entities.⁴ Similarly, to help ensure covered entities receive discounts to which they are entitled, HRSA has issued guidance (referred to as “HRSA’s nondiscrimination guidance” throughout this statement) prohibiting drug manufacturers from distributing drugs in ways that would discriminate against covered entities compared to non-340B health care providers, such as by imposing minimum purchase requirements or other restrictive conditions.⁵

In a September 2011 report, we identified inadequacies in HRSA’s oversight of this program and recommended actions that should be taken to improve oversight and ensure appropriate use of the program.⁶ Since then, we have been monitoring HRSA’s progress in addressing our recommendations, including at a March 24, 2015, hearing before your Subcommittee on Health.⁷ My statement today will describe HRSA actions in response to GAO recommendations to address (1) weaknesses in oversight of the 340B program and (2) the lack of clarity in program guidance. The statement will also (3) describe ongoing GAO work regarding the 340B program and HRSA oversight.

For this statement, we obtained information and documentation from HRSA officials about any significant program updates, and steps they

⁴42 U.S.C. § 256b(a)(5)(B).

⁵Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 58 Fed. Reg. 68922 (Dec. 29, 1993).

⁶See GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Washington, D.C.: September 23, 2011).

⁷See GAO, *Drug Discount Program: Status of GAO Recommendations to Improve 340B Drug Pricing Program Oversight*, GAO-15-455T (Washington, D.C.: March 24, 2015).

have taken to implement our 2011 recommendations. More detailed information on the objectives, scope, and methodology for our 2011 report can be found in that report.⁸ We conducted our work for the 2011 report from September 2010 to September 2011, and updated this work in February and March 2015 and again in June and July 2017. The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

The 340B Program was created following the enactment of the Medicaid Drug Rebate Program and gives 340B covered entities discounts on outpatient drugs comparable to those made available to state Medicaid agencies.⁹ HRSA is responsible for administering and overseeing the 340B Program.

Program Participants

Eligibility for the 340B Program, which is defined in the PHSA, has expanded over time, most recently through the Patient Protection and Affordable Care Act, which extended eligibility to additional types of hospitals.¹⁰ Entities generally become eligible by receiving certain federal grants or by being one of six hospital types. Eligible grantees include clinics that offer primary and preventive care services, such as Federally Qualified Health Centers, clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, and state-operated AIDS Drug Assistance Programs, which serve as a "payer of last resort" to cover the cost of providing HIV-related medications to certain low-income individuals. Eligible hospitals include certain children's hospitals, free-standing cancer hospitals, rural referral centers, sole

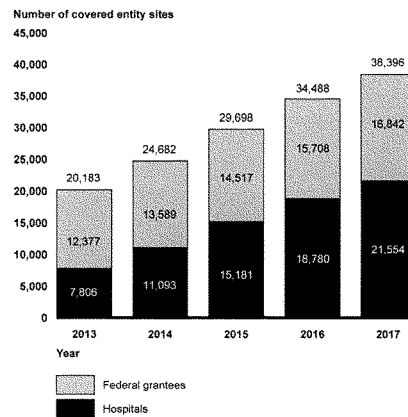
⁸GAO-11-836.

⁹The Medicaid Drug Rebate Program was established through the *Omnibus Budget Reconciliation Act of 1990* and requires drug manufacturers to pay rebates to states as a condition of having their drugs covered by Medicaid. Pub. L. No. 101-508 § 4401, 104 Stat. 1388, 1388-143 (adding 42 U.S.C. § 1396r-8).

¹⁰See Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010) as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 2302, 124 Stat. 1029, 1082.

community hospitals, critical access hospitals, and general acute care hospitals that serve a disproportionate number of low-income patients, referred to as disproportionate share hospitals (DSH).¹¹ To become a covered entity and participate in the program, eligible entities must register with HRSA and be approved. Entity participation in the 340B program has grown over time to include more than 38,000 entity sites, including more than 21,000 hospital sites and nearly 17,000 federal grantee sites (see fig. 1).

Figure 1: Growth in Covered Entity Sites, 2013 to 2017



Source: GAO analysis of Health Resources and Services Administration data. | GAO-17-749T
 Note: Numbers are as of January 1 of each year.

¹¹ Medicare DSH hospitals receive an additional Medicare payment based on their DSH patient percentage, which is a statutory formula created to identify hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients.

To be eligible for the 340B Program hospitals must meet certain requirements intended to ensure that they perform a government function to provide care to the medically underserved. First, hospitals generally must meet specified DSH adjustment percentages to qualify.¹² Additionally, they must be (1) owned or operated by a state or local government, (2) a public or private nonprofit corporation that is formally delegated governmental powers by a unit of state or local government, or (3) a private, nonprofit hospital under contract with a state or local government to provide health care services to low-income individuals who are not eligible for Medicaid or Medicare.¹³

All drug manufacturers that supply outpatient drugs are eligible to participate in the 340B Program and must participate in order to have their drugs covered by Medicaid. To participate, manufacturers are required to sign a pharmaceutical pricing agreement with HHS in which both parties agree to certain terms and conditions.

Program Structure, Operation, and Key Requirements

The 340B price for a drug—often referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a participating drug manufacturer may charge covered entities.¹⁴ Covered entities must follow certain requirements as a condition of participating in the 340B Program. For example

- covered entities are prohibited from subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B price and a rebate through the Medicaid Drug Rebate Program.¹⁵
- covered entities are also prohibited from diverting any drug purchased at the 340B price to an individual who does not meet HRSA's definition of a patient. This definition, issued in 1996, outlines three criteria that generally state that diversion occurs when 340B

¹²Critical access hospitals are exempt from this requirement.

¹³According to HRSA, a hospital is said to be "formally granted governmental powers" when the state formally delegates to the hospital a type of power(s) usually exercised by the state, for the purpose of providing health care services to the medically indigent population of the state.

¹⁴Manufacturers may sell a drug at a price that is lower than the ceiling price. As such, covered entities may negotiate prices below the ceiling price.

¹⁵ 42 U.S.C. § 256b(a)(5)(A).

discounted drugs are given to individuals who are not receiving health care services from covered entities or are only receiving non-covered services, such as inpatient hospital services.¹⁶ (See table 1 for more information on HRSA's definition of an eligible patient.) Covered entities are permitted to use drugs purchased at the 340B price for all individuals who meet the 340B Program definition of a patient regardless of whether they are low-income, uninsured, or underinsured.

Table 1: Health Resources and Services Administration's (HRSA) Definition of a Patient Eligible for Discounted Drugs under the 340B Program

Criteria for patient eligibility:^a

1. The covered entity has established a relationship with the individual such that the covered entity maintains records of the individual's health care.
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.^b
3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally Qualified Health Center look-alike status has been provided.^c

Source: GAO analysis of HRSA guidance. | GAO-17-749T

Notes: HRSA guidance on the definition of a patient eligible for discounted drugs under the 340B Program was issued in 1996. See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

^aThese criteria do not apply to AIDS Drug Assistance Programs; rather an individual enrolled in an AIDS Drug Assistance Program will be considered a patient of that program.

^bAn individual is not considered a patient if the only health care service received from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

^cDisproportionate share hospitals are exempt from this requirement. Not all federally qualified health centers receive federal grants. Providers that meet all of the requirements for the health center program but do not receive federal grants are referred to as look-alikes and are eligible to participate in the 340B program.

A covered entity typically purchases and dispenses 340B drugs through pharmacies—either through an in-house pharmacy, or through the use of a contract pharmacy arrangement, in which the covered entity contracts with an outside pharmacy to dispense drugs on its behalf. The adoption and use of contract pharmacies is governed by HRSA guidance. HRSA's original guidance permitting the use of contract pharmacies limited their use to covered entities that did not have in-house pharmacies and

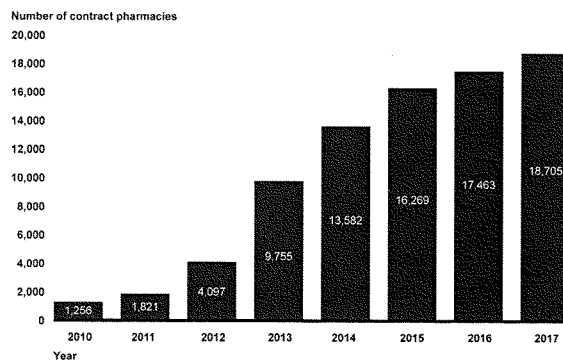
¹⁶See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996).

allowed each covered entity to contract with only one outside pharmacy.¹⁷ However, March 2010 guidance lifted the restriction on the number of pharmacies with which a covered entity could contract.¹⁸ Since that time, the number of unique contract pharmacies has increased significantly, from about 1,300 at the beginning of 2010 to around 18,700 in 2017 (see fig. 2); and, according to HRSA data, in 2017, there were more than 46,000 contract pharmacy arrangements.¹⁹ HRSA guidance requires a written contract between the covered entity and each contract pharmacy. Covered entities are responsible for overseeing contract pharmacies to ensure compliance with prohibitions of drug diversion and duplicate discounts. HRSA guidance indicates that covered entities are "expected" to conduct annual independent audits of contract pharmacies, leaving the exact method of ensuring compliance up to the covered entity.

¹⁷Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996).

¹⁸Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010).

¹⁹Contract pharmacies may have arrangements to dispense drugs for more than one entity. HRSA data indicates that there were 46,174 contract pharmacy arrangements—arrangements between a covered entity site and a pharmacy—as of January 1, 2017. However, the total number of contract pharmacy arrangements is likely higher, as HRSA does not require entities to report all arrangements to the agency.

Figure 2: Growth in Contract Pharmacy Participation, 2010 to 2017

Source: Health Resources and Services Administration. | GAO-17-749T

Note: Data represent the number of unique contract pharmacies participating in the program as of January 1 of each year. Contract pharmacies may have arrangements to dispense drugs for more than one entity.

Drug manufacturers also must follow certain 340B Program requirements. For example, HRSA's nondiscrimination guidance prohibits manufacturers from distributing drugs in ways that discriminate against covered entities compared to other providers. This includes ensuring that drugs are made available to covered entities through the same channels that they are made available to non-340B providers, and not conditioning the sale of drugs to covered entities on restrictive conditions, which would have the effect of discouraging participation in the program.

HRSA Has Implemented GAO's Recommendation to Improve Its Oversight of the 340B Program by Conducting Audits

In our September 2011 report, we found that HRSA's oversight of the 340B Program was weak because it primarily relied on covered entities and manufacturers to police themselves and ensure their own compliance with program requirements.²⁰ Upon enrollment into the program, HRSA requires participants to self-certify that they will comply with applicable 340B Program requirements and any accompanying agency guidance, and expects participants to develop the procedures necessary to ensure and document compliance, informing HRSA if violations occur. HRSA officials told us that covered entities and manufacturers could also monitor each other's compliance with program requirements, but we found that, in practice, participants could face limitations to such an approach.

Beyond relying on participants' self-policing, we also found that HRSA engaged in few activities to oversee the 340B Program and ensure its integrity, which agency officials said was primarily due to funding constraints. Further, although HRSA had the authority to conduct audits of program participants to determine whether program violations had occurred, at the time of our 2011 report, the agency had never conducted such an audit.

In our 2011 report, we concluded that changes in the settings where the 340B Program was used may have heightened the concerns about the inadequate oversight we identified. In the years leading up to our report, the settings where the 340B Program was used had shifted to more contract pharmacies and hospitals than in the past, and that trend has continued in recent years. We concluded that increased use of the 340B Program by contract pharmacies and hospitals may have resulted in a greater risk of drug diversion to ineligible patients, in part because these facilities were more likely to serve patients that did not meet the definition of a patient of the program.

To address these oversight weaknesses, we recommended that the Secretary of HHS instruct the administrator of HRSA to conduct selective audits of covered entities to deter potential diversion. In response to that recommendation, in fiscal year (FY) 2012, HRSA implemented a systematic approach to conducting annual audits of covered entities that

²⁰GAO-11-836.

is outlined on its website.²¹ Now numbering 200 per year, HRSA audits include entities that are randomly selected based on risk-based criteria (approximately 90 percent of the audits conducted each year), and entities that are targeted based on information from stakeholders (10 percent of the audits conducted). (See table 2 for the number of audits conducted by HRSA from FY 2012-2017.)

Table 2: Audits of Covered Entities by the Health Resources and Services Administration (HRSA), FY 2012-2017

Fiscal year	Total audits
2012	51
2013	94
2014	99
2015	200
2016	200
2017 (planned)	200
Total	844

Source: HRSA, | GAO-17-749T

As a result of the audits already conducted, HRSA has identified instances of non-compliance with program requirements, including violations related to drug diversion and the potential for duplicate discounts. The agency has developed a process to address non-compliance through corrective action plans. The results of each year's audits are available on HRSA's website.

²¹See <https://www.hrsa.gov/opa/programintegrity/index.html>, accessed June 30, 2017.

HRSA Implemented One of Three GAO Recommendations to Clarify Program Guidance

In our 2011 report, we found that HRSA's guidance on three key program requirements lacked the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others' compliance, and raising concerns that the guidance could be interpreted in ways that were inconsistent with its intent.²²

First, we found that HRSA's nondiscrimination guidance was not sufficiently specific in detailing practices manufacturers should follow to ensure that drugs were equitably distributed to covered entities and non-340B providers when distribution was restricted.²³ Some stakeholders we interviewed for the 2011 report, such as covered entities, raised concerns about the way certain manufacturers interpreted and complied with the guidance in these cases. We recommended that HRSA further clarify its nondiscrimination guidance for cases in which distribution of drugs is restricted and require reviews of manufacturers' plans to restrict distribution of drugs at 340B prices in such cases. In response, HRSA issued a program notice in May 2012 that clarified HRSA's policy for manufacturers that intend to restrict distribution of a drug and provided additional detail on the type of information manufacturers should include in such restricted distribution plans.²⁴

In addition, we found a lack of specificity in HRSA's guidance on two other issues—the definition of an eligible patient and hospital eligibility for program participation. Specifically, we found that

- HRSA's guidance on the definition of an eligible patient lacked the necessary specificity to clearly define the various situations under which an individual was considered eligible for discounted drugs through the 340B Program. As a result, covered entities could interpret the definition either too broadly or too narrowly. At the time of our report, agency officials told us they recognized the need to provide additional clarity around the definition of an eligible patient, in part because of concerns that some covered entities may have interpreted the definition too broadly to include non-eligible

²²GAO-11-836.

²³Restricted distribution may occur when there is a shortage in drug supply or when shortages are anticipated.

²⁴HRSA Drug Pricing Program Notice, Release No. 2011-1.1 (May 23, 2012).

individuals, such as those seen by providers who were only loosely affiliated with a covered entity.

- HRSA had not issued guidance specifying the criteria under which hospitals that were not publicly owned or operated could qualify for the 340B Program.²⁵ For example, we found HRSA guidance lacking on one of the ways hospitals could qualify for the program, namely by executing a contract with a state or local government to provide services to low-income individuals who are not eligible for Medicaid or Medicare. Specifically, we found that HRSA did not outline any criteria that must be included in such contracts, such as the amount of care a hospital must provide to these low-income individuals, and did not require the hospitals to submit their contracts for review by HRSA.²⁶ As a result, hospitals with contracts that provided a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not have been what the agency intended.

Given the lack of specificity in these areas, we recommended that HRSA (1) finalize new, more specific guidance on the definition of an eligible patient, and (2) issue guidance to further specify the criteria that hospitals not publicly owned or operated must meet to be eligible for the 340B program. HRSA agreed with these recommendations and had planned to address them in a comprehensive 340B Program regulation that it submitted to the Office of Management and Budget for review in April 2014. However, HRSA withdrew this proposed regulation in November 2014 following a May 2014 federal district court ruling that the agency had not been granted broad rulemaking authority to carry out all the provisions of the 340B program.²⁷ After this ruling, the agency issued a proposed omnibus guidance in August 2015 to interpret statutory requirements for the 340B program in areas where it did not have explicit rulemaking authority, including further specificity on the definition of a patient of a

²⁵We use the term "hospitals that are not publicly owned or operated" to refer to public and private nonprofit corporations as well as private, nonprofit hospitals that may be eligible for the 340B Program. The term does not include private, for-profit hospitals as these hospitals are not eligible for the 340B Program.

²⁶HRSA officials we interviewed for the September 2011 report told us that contracts were selectively reviewed if further clarification was necessary.

²⁷See *Pharm. Research & Mfrs. of Am. v. United States HHS*, No. 13-1501, 2014 U.S. Dist. LEXIS 70894 (D.D.C. May 23, 2014).

covered entity and hospital eligibility for 340B program participation.²⁸ However, in January 2017, the agency withdrew the guidance following the administration's January 20 memorandum directing agencies to withdraw or postpone regulations and guidance that had not yet taken effect.²⁹ In July 2017, HRSA indicated that it was working with HHS to determine next steps regarding the proposed Omnibus Guidance, which included the patient definition, but that it was unable to further clarify guidance on hospital eligibility without additional authority.

GAO Has Ongoing Work Examining HRSA Oversight of 340B Contract Pharmacies

Given the increase in the number of contract pharmacies in the 340B Program and concerns that contract pharmacy arrangements present an increased risk to the integrity of the program, we were asked to review contract pharmacy use under the 340B Program. For this review, we are planning to address the following four questions.

- To what extent do the various types of covered entities use contract pharmacies and where are the pharmacies located?
- What, if any, financial arrangements do covered entities have with contract pharmacies and third-party administrators related to the administration and dispensing of 340B drugs, and how, if at all, this varies by entity type?³⁰
- To what extent do covered entities provide low-income, uninsured patients with discounts on drugs dispensed by contract pharmacies?
- How, if at all, do covered entities and HRSA ensure compliance with 340B program requirements at contract pharmacies?

We are in the early stages of this work, and we expect to issue a future report on 340B contract pharmacies.

²⁸See 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300 (Aug. 28, 2015).

²⁹See Memorandum for the Heads of Executive Departments and Agencies, Regulatory Freeze Pending Review, 82 Fed. Reg. 8346 (Jan. 24, 2017).

³⁰Third-party administrators are private companies that some covered entities contract with to manage systems for patient eligibility, program finances, and 340B inventory.

Chairman Murphy, Ranking Member DeGette, and Members of the Committee, this concludes my statement. I would be pleased to respond to any questions you may have.

**GAO Contacts and
Staff
Acknowledgments**

For further information about this statement, please contact Debra A. Draper at (202) 512-7114 or draperd@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony. Key contributors to this statement were Michelle Rosenberg, Assistant Director; Rotimi Adebajo, Jennie Apter, and Amanda Cherrin.

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<http://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <http://www.gao.gov> and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

Connect with GAO

Connect with GAO on Facebook, Flickr, LinkedIn, Twitter, and YouTube. Subscribe to our RSS Feeds or E-mail Updates. Listen to our Podcasts. Visit GAO on the web at www.gao.gov and read The Watchblog.

To Report Fraud, Waste, and Abuse in Federal Programs**Contact:**

Website: <http://www.gao.gov/fraudnet/fraudnet.htm>

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Katherine Siggerud, Managing Director, siggerudk@gao.gov, (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800, U.S. Government Accountability Office, 441 G Street NW, Room 7149, Washington, DC 20548

Strategic Planning and External Liaison

James-Christian Blockwood, Managing Director, spel@gao.gov, (202) 512-4707, U.S. Government Accountability Office, 441 G Street NW, Room 7814, Washington, DC 20548



Please Print on Recycled Paper.

Mr. MURPHY. Thank you, Doctor.

I now recognize myself for 5 minutes for questions.

Captain Pedley, let me just start off with this. There is a lack of clarity in how the intent of the program is, which you outlined in your testimony in your documents there.

The absence of reporting requirements and specific mandates on how savings must be spent—can you elaborate a little bit more on what that impact is?

Ms. PEDLEY. So the statute is silent regarding how covered entities have to use their savings. Therefore, HRSA doesn't have authority to require what these entities are doing with their savings.

Mr. MURPHY. So is that savings—does it go into the general fund or the hospital or clinic or a separate account so even if you were to audit that separate account you could see where that money goes? Or is there no way to do that?

Ms. PEDLEY. I don't have insight into how a hospital may manage those funds.

Mr. MURPHY. OK. So you wouldn't know. But you don't audit that anyway. So—

Ms. PEDLEY. Correct.

Mr. MURPHY. But these entities are generally supposed to serve specific vulnerable populations. But people who may go into a hospital or entity that has a 340B program there is not a means test by which says you can't go to this program based upon your income. They could come in regardless of income, correct?

Ms. PEDLEY. Correct. The statute is silent as well as to whether a patient is insured or uninsured. They just have to meet our patient eligibility guidance.

Mr. MURPHY. And the patient eligibility guidance, I understand, is that records have to be kept there and the doctor treating them has to work there?

Ms. PEDLEY. Yes. There have to be records and HRSA audits those records.

Mr. MURPHY. OK. So do community health centers use a sliding scale to discount policy to determine a patient's ability to pay?

Ms. PEDLEY. I know under their separate grant requirements they do have different things in place. I am not familiar with those.

Mr. MURPHY. OK.

Ms. PEDLEY. But that is under their grant requirements, not under the 340B statute.

Mr. MURPHY. My assumption is they would and that would be one way of passing on savings. Do hospitals use a sliding scale to discount policy to determine a patient's ability to pay?

Ms. PEDLEY. I don't have insight into that either as they are not required under the 340B statute to pass on the savings.

Mr. MURPHY. But hospitals and other covered entities can acquire the drugs at a 25 to 50 percent discount, right?

Ms. PEDLEY. Correct.

Mr. MURPHY. And then charge the patients full price for the same drug?

Ms. PEDLEY. So the amount that they charge the patient after they receive that discount, again, is a decision made at the hospital. The price that they charge is outside of the 340B statute.

Mr. MURPHY. So if someone who is very, very low income, struggling, could come in and purchase it under the intent of the program.

But at that same clinic or hospital that was brought up before about oncology, someone could be in there—for all we know could be a multi-billionaire and also they would be eligible to—the drug would be eligible.

The hospital could buy at a discount and sell it to the person at the full price?

Ms. PEDLEY. So the statute is silent again on how the savings are used and whether the patient is insured or uninsured. If the patient is insured, then the entity would bill the insurer at the higher rate and then obtain that revenue to stretch their scarce federal resources.

Mr. MURPHY. And so what happens, however, is that because they are not required to collect this data, you don't know what's really happening. If you audit, you don't know, for example, how many people may come in there, what their income level is because that is not a required thing for the eligible patient, correct?

Ms. PEDLEY. That's correct. HRSA does not audit that information as it is outside of our authority.

Mr. MURPHY. And the money that comes through these savings, you have no idea where that money goes because that information is not collected and it is—correct?

Ms. PEDLEY. There are no requirements in the statute so we do not—

Mr. MURPHY. Do they voluntarily say, here's how we spent the money? Does anybody do that?

Ms. PEDLEY. They do not voluntarily submit that information to HRSA.

Mr. MURPHY. And since the accounts may not be separate as far as you know, even if they put the money in the general fund that—we couldn't even trace that, how that is done?

Ms. PEDLEY. HRSA would not have access to that information. Again, I reiterate for the grantees, however, they are required under their grant requirements to report 340B program savings as income and put that back into their grant.

Mr. MURPHY. OK. But is there any data which would show the level of charity care they are providing? Anything that they are required to show you?

Ms. PEDLEY. They do not share anything with HRSA. They may report charity care information on their cost reports that is submitted to CMS.

Mr. MURPHY. And we don't know if that charity care money came from the 340B or came from something else?

Ms. PEDLEY. Yes, HRSA would not know that.

Mr. MURPHY. So as I understand it so far with the vague guidelines of eligibility for patients, the intent of the program, of course, to help the indigent population—good.

The idea that other people who may not fit that definition may still have the hospital or clinic purchasing at a discount and can use that money in any way, shape, or form and you have no way of finding out and they are not required to keep data and the books

aren't kept in such a way that anybody could trace it if they wanted to?

Ms. PEDLEY. Yes. The statute, again, does not in any way mention what covered entities—

Mr. MURPHY. OK.

Ms. PEDLEY [continuing]. Do with that savings or that they have to report it to HRSA.

Mr. MURPHY. And operate under the assumption they are all doing good works but we don't know, and since 60 to 80 percent have some problems, we will see.

Ms. DeGette, 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

I thought your line of questioning was quite interesting and I would like to follow up on it a little bit.

The chairman was asking appropriately, I think, what do hospitals do with the money. I don't think we have anybody here who would be able to answer that question, right?

OK. So none of the three of you can answer that question. I would assume there is probably somebody who can answer that question and maybe we should have a follow-up hearing and have some people from the hospitals come and talk about what they do with that money.

Dr. Draper, I do know that one of the GAO findings was that—well, first of all, is the GAO aware of a practice with hospitals where they get the discounts under 340B and then they pass those discounts along to billionaires and things like that? Have you found any evidence of that?

Ms. DRAPER. We have not looked at that specifically.

And getting back to your earlier question—

Ms. DEGETTE. Yes.

Ms. DRAPER. In our 2011 work we did interview a small number of covered entities to ask them what they did with the revenues and most said they are not required to report that.

Ms. DEGETTE. Right.

Ms. DRAPER. So what they told us was that they use the moneys to expand services to patients and to provide more comprehensive services.

Ms. DEGETTE. So the limited evidence you got seemed to indicate they were using that for the original intended purpose?

Ms. DRAPER. Yes. It was very limited information and—

Ms. DEGETTE. Number one, Mr. Chairman, I think we should try to get some hospitals in here to talk to us, but number two, I think your inference is correct.

We probably do need to get more controls and that is why I said in my opening statement that we may need to have more legislative reporting and more transparency because you can't have a program where nobody knows what's going on.

But let us get back for a minute to the original purpose of the 340B program. Captain Pedley, what the 340B program was intended to do was to help providers stretch scarce resources and give services to people who are uninsured or lack insurance altogether. Is that right?

Ms. PEDLEY. Yes. From report language, the intent of the program was for these covered entities to be able to purchase the

drugs at a discount in order to stretch their resources and provide more care to patients.

Ms. DEGETTE. Right. So if people didn't have this source of revenue, hospitals, assuming they are using the revenue for the originally intended purpose, they might have to cut back on services that they would provide to these underserved populations. Is that correct?

Ms. PEDLEY. So if the program were not——

Ms. DEGETTE. A yes or no will work.

Ms. PEDLEY. Yes.

Ms. DEGETTE. Thanks.

Now, so, Dr. Draper, I understand that in the GAO audits you found some weaknesses in HRSA's ability to oversee the program and also you found that the agency needs to issue guidance that defines a 340B patient and clarify the standard for hospital eligibility. Are those in general your concerns?

Ms. DRAPER. Well, to give you an example, the definition of a patient is very ambiguous. It is that the patient has an established relationship with the entity and the entity maintains the medical records and that the provider of services for that entity is either employed or under contract arrangement or some other type of arrangement.

So we had concerns about the language about like some other type of arrangement——

Ms. DEGETTE. Right.

Ms. DRAPER [continuing]. What specifically does that mean, and I think it has been interpreted very broadly.

Ms. DEGETTE. So let me ask you, do you think the agency has authority under the current statutory language to tighten those definitions up or do you think that we need to do something with the statute?

Ms. DRAPER. Well, since 1992 the agency has issued program guidance to try to clarify the rules of the program. So we are a little confused about why. I think there is some concern that they need some regulatory authority versus having guidance and——

Ms. DEGETTE. OK. So we might have to go and look at the statute.

Ms. DRAPER. Perhaps.

Ms. DEGETTE. Yes. OK.

And Ms. Bliss, I just wanted to ask you quickly what tools or authorities do you believe HRSA needs in order to efficiently administer the 340B program?

Ms. BLISS. Thank you.

We believe that increasing transparency and clarity around the program rules is very important, and while I can't offer a legal opinion on HRSA's authority, our understanding is they may need additional authority from Congress to do this.

Ms. DEGETTE. Great. Thank you.

Thanks, Mr. Chairman. I yield back.

Mr. MURPHY. Thanks. Can I follow up on that quickly?

With regard to those definitions of entities, are any of you receiving letters, pressures from other organizations, hospital associations, pharma, et cetera, on recommendations for these changes?

Ms. DRAPER. We have not.

Mr. MURPHY. You have not? Ms. Bliss.

Ms. BLISS. No, not at all.

Mr. MURPHY. Captain Pedley.

Ms. PEDLEY. So when we proposed in August 2015 our omnibus guidance, patient definition was a part of that and we did receive over 1,200 comments related to the entire guidance but within those specifically to the patient definition.

Mr. MURPHY. OK. Just with regard to there might be some on this committee who would like to see some of those.

Ms. PEDLEY. Yes. I agree.

Mr. MURPHY. We will sharpen our question to you. Thank you very much.

Chairman Walden.

Mr. WALDEN. Thank you, Mr. Chairman. Thanks for having this oversight hearing.

And I just want to follow up on a couple of things. Do we or do we not know or audit how the savings are spent? That seems to be one of the issues.

We all believe that everybody is a good actor and the money is going to the people most in need, as well as savings.

But I also am not clear that HRSA actually—that there is a clear definition of how the money should be spent or that we track the money.

Is that correct?

Ms. PEDLEY. So the statute is silent as to how savings are used. Therefore, HRSA does not audit or have access to that information.

Mr. WALDEN. So we really don't have a trail of bread crumbs as to—you know how much it saved, right? Or do you?

Ms. PEDLEY. The discount on the drug?

Mr. WALDEN. Right.

Ms. PEDLEY. So it is on average between 25 to 50 percent but it depends on the specific drug.

Mr. WALDEN. Do we know if those savings get passed specifically back to people who need reduction in prices on the drugs?

Ms. PEDLEY. The statute is silent in that area. So HRSA does not have that information.

Mr. WALDEN. OK. So we don't know that.

And of those savings, could the 340B hospitals take that money and use it for good things but not necessarily back to the same person that is buying the drugs?

Ms. PEDLEY. Because the statute is silent—

Mr. WALDEN. Silent.

Ms. PEDLEY [continuing]. We don't have access to that.

Mr. WALDEN. OK. All right.

And these are issues I think both of you have raised, right, from GAO and from OIG that there is just lack of clarity here?

Ms. DRAPER. Yes. We don't know how the savings are used. The entities are not required to keep that information or to track it.

We are currently doing some work on looking at contract pharmacies and we are going to be looking at things like discounts that are being provided to patients. So—

Mr. WALDEN. OK.

Ms. DRAPER. As far as the savings, there are really no requirements and most of the entities in our 2011 work that we talked to were not able to provide that information.

Mr. WALDEN. So could a 340B get the savings from the drug manufacturer and not pass those on to the individual that actually charged the individual through their pharmacies, like, the retail price for that drug?

Ms. DRAPER. I think that is very possible. There is just no way to know—

Mr. WALDEN. We don't know.

Ms. DRAPER [continuing]. Without the transparency around that.

Mr. WALDEN. All right.

Yesterday, HRSA's website listed a total of 41,132 registered sites. That is an increase of 3,636 registered sites since the budget justification was released.

So from HRSA's perspective, do you know how many of these 3,636 sites are new unique covered entities and how many are these so-called child sites?

Ms. PEDLEY. I would have to go back and look at the specifics of the data as to how many are new—the main facility or a child site, as you mentioned.

Mr. WALDEN. Yes. Well, you just don't know off the top of your head?

Ms. PEDLEY. Correct.

Mr. WALDEN. OK. All right.

Ms. PEDLEY. But we have that information.

Mr. WALDEN. And overall you are seeing a faster growth rate for the new covered entities or new child sites? Which are you seeing the fastest growth rate for?

Ms. PEDLEY. I would have to go back again and compare the growth rate of the new entities versus child sites.

Mr. WALDEN. OK.

Ms. PEDLEY. We do have that.

Mr. WALDEN. And how many manufacturers are participating in the 340B program?

Ms. PEDLEY. Over 600.

Mr. WALDEN. OK. And how has that number changed in the last few years?

Ms. PEDLEY. It stays about the same. So the manufacturers that participate in the program are based on the manufacturers that participate in the Medicaid program.

They are required to participate in 340B if they are in Medicaid. Again, so we monitor when manufacturers enter into the Medicaid program to ensure that they also sign an agreement with HRSA to participate in the 340B program.

Mr. WALDEN. And I don't know if this is a fair question to ask you, Captain, but it is my understanding that HRSA was given an additional \$6 million in funding beginning in FY 2014 and I guess the question is how much does HRSA now receive in funding to oversee the program and is that enough?

Ms. PEDLEY. So we did receive an additional \$6 million in fiscal year '15 for program integrity efforts and information technology as well.

We continue to remain at the \$10.2 million in total and that is in our proposed budget as well for fiscal year '18 in order to maintain our level of oversight in the program.

Mr. WALDEN. And you have got how many staff involved?

Ms. PEDLEY. We currently have 16 FTEs.

Mr. WALDEN. Do they have other responsibilities other than just overseeing 340B?

Ms. PEDLEY. So they specifically work on the 340B program anywhere from our information technology systems to registering entities in the program to specifically the audit function.

Mr. WALDEN. So they are focused on 340B exclusively?

Ms. PEDLEY. Yes.

Mr. WALDEN. OK. All right.

This has been most helpful. Obviously, there are some statutory issues here and some clarity issues on who is a patient and transparency and who gets the benefit from the program designed to help patients in one way or another.

So, Mr. Chairman, thank you for holding this hearing. I appreciate the input of our talented witnesses.

Mr. MURPHY. Thank you.

I now recognize the gentleman from New Jersey, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Mr. Chairman.

The 340B program is a critical component of the safety net that serves the most vulnerable among us and 340B drug discounts help safety net providers make the most of the limited resources they receive.

As a result, they are able to reach more eligible patients and provide those patients with more comprehensive health services, and I believe in both protecting 340B and improving the integrity of the program to ensure it remains strong for the future.

My questions are, Captain Pedley, could you describe how this program helps safety net hospitals and other covered providers give care to needy populations? In other words, the 340B, if you could answer that question.

Ms. PEDLEY. So the intent of the program was for these entities defined in statute to be able to purchase the drugs at a discount so they can stretch those scarce federal resources.

Once they are eligible for the program and listed on our database and we validate to ensure they are eligible for the statute they are then able to purchase these drugs at a discount, typically 25 to 50 percent lower than what they would have otherwise paid.

Mr. PALLONE. And so the discounts help ensure that all individuals including the under insured and the uninsured have access to care. Is that a correct statement on my part?

Ms. PEDLEY. Yes, based on the intent of the program.

Mr. PALLONE. All right.

Now, Captain, can you please describe how the 340B drug discounts generate savings for providers while expanding services for patients?

Ms. PEDLEY. So the savings in the program are generated on the up front discounts that they receive on the drug.

In addition, if the patient is insured they bill the insurer at the higher rate in order to create revenue to provide then the care to those that do not have insurance there or the ability to pay.

Mr. PALLONE. OK, and I know some members have already expressed concerns that there is not sufficient transparency with respect to how some 340B hospitals use their money. What actions is HRSA taking, if any, to improve transparency in the program?

Ms. PEDLEY. The statute is silent on the savings but in the fiscal year '18 president's budget we did propose to intend to work with Congress on a legislative proposal to ensure the benefit of the program does benefit the low-income uninsured populations.

Mr. PALLONE. OK.

I wanted to ask Dr. Draper what are the most important actions out of GAO's recommendations to improve program integrity in 340B and how should Congress prioritize?

Ms. DRAPER. Well, I think one of the key pieces is really clarifying the intent of the program. The intent was set up 25 years ago and, I think there is a misperception that it does.

It doesn't explicitly talk about uninsured or under insured patients—to receive benefits through the program. That is implied, depending on the types of covered entities. So that is one issue.

The other issue is really clarifying the definition of a patient. That would go a long way as well as hospital criteria—the criteria to participate. So those are the weaknesses that we currently see remaining that would really help improve the integrity of the program.

Mr. PALLONE. OK. So from what I am hearing, the 340B program does play a valuable role in our efforts to provide a robust safety net for vulnerable patients and while more can be done to improve transparency those efforts should be tailored towards helping the program serve more needy patients.

So I want to thank you all for being here this morning and the comments, I think they are very helpful.

I yield back.

Mr. MURPHY. Gentleman yields now.

I now recognize Mr. Barton or 5 minutes.

Mr. BARTON. Thank you, Mr. Chairman.

This is a difficult hearing. We have got a program that I think both political parties strongly support. I have got a number of federally qualified health facilities and DSH hospitals in my district that use 340B and it is an integral part of the care they provide to the low-income population.

But it is a program that has just grown exponentially and, quite frankly, I think HRSA has done a pretty amazing job, given how many people you have—24 people at one time. That is about this subcommittee. You did 200 audits. That's 10 per month per person. I couldn't do 10 audits a month if I were a CPA. And yet, nobody really knows what's going on in the program because it is so big.

I don't even understand what we are talking about when you talk about the money. So I am going to ask a very elementary question and see if you can explain it to me. If the regular price for a drug from a manufacturer is \$10—I am making it as easy as I can—and the average discount for 340B is 50 percent, that means that the entity that is participating in the 340B program is charged

\$5. Is that right? The hospital pharmacy, their cost is \$5. Now, if they prescribe that to an outpatient, what does Medicaid pay for that prescription? Do they pay \$5? Do they pay \$10? Do they pay \$7.50? In other words, what, if any, is the markup? Can anybody answer that?

Ms. PEDLEY. So, first, with the ceiling price, the price that an entity pays is actually set in statute. The calculation is set based on——

Mr. BARTON. I don't need to know that. I am using my example. Ten dollars is what the retail price would be—the normal price if it wasn't a 340B drug and you said the discount is 25 to 50 percent. So I made it 50. So the price is \$5. What I want to know is the patient who gets that drug—whoever is paying for it, the patient or Medicaid—what do they pay? Do they pay \$5? Do they pay \$10? Do they pay \$15? Do they pay something in between?

Ms. PEDLEY. So if the patient has insurance they would pay their standard co-pay. If they are uninsured——

Mr. BARTON. If they are covered by Medicaid.

Ms. BLISS. So CMS has a rule for state Medicaid programs that they would reimburse at that \$5 plus a dispensing fee.

Mr. BARTON. Plus a dispensing fee. But there is no profit?

Ms. BLISS. Not in the Medicaid context.

Mr. BARTON. OK. So, technically, whatever the discount is that is passed through?

Ms. BLISS. Yes, to the Medicaid——

Mr. BARTON. But you have no way to prove that it really is passed through?

Ms. BLISS. State Medicaid agencies don't currently have access to those ceiling prices.

Mr. BARTON. So nobody knows?

Ms. BLISS. There is no check and balance.

Mr. BARTON. It is voluntary compliance. I guarantee you people are abusing that. I guarantee it. But let us forget that. Let us forget that. So we really have no controls on that end. If the dispensing pharmacy—they get the discount but let us say they charge Medicaid the regular rate, \$10. So they have got a profit of \$5. Is that illegal under current law? Are they required to pass it through or can they keep it and in the best case use it to defray the cost of another patient?

Ms. DRAPER. If it is not required it is how they pass or whether they pass on discounts. Unless it is part of their federal grants for a federally qualified health center their grant may require them to pass on discounts but not for all facilities.

Mr. BARTON. So even though they are getting a lower rate they could charge the higher rate and use that within their facility for some other purpose?

Ms. DRAPER. That is correct. It is not clear how that is being used.

Mr. BARTON. It is not illegal. I am just trying to educate the subcommittee how screwed up this program is.

My last question—my time has expired—if we created a whistle blower option so that anybody in the country could turn somebody in if they think there is abuse and if there is abuse they got to keep

some of the savings that was discovered would that help police the program?

Ms. DRAPER. Well, I think you would have to make sure that the rules are clear as to what—it goes back to patient eligibility, hospital eligibility criteria.

I think some of that ambiguity is——

Mr. BARTON. I am not even going down that trail.

Ms. DRAPER. Yes, but I think this——

Mr. BARTON. I am assuming everybody in the program is allowed to be in the program.

Ms. DRAPER. Right. But I think those rules are not clear. So people have interpreted it very differently. So until the rule is clear——

Mr. BARTON. It is a mess.

Ms. DRAPER [continuing]. It is really difficult to do that, I think.

Mr. BARTON. This is a great opportunity for this subcommittee. On a bipartisan basis, we all support the 340B program. But it has grown topsy-turvy. We really need to put the best minds of this subcommittee on a bipartisan basis and see if we can come up with some solutions.

With that, I yield back.

Mr. MURPHY. I will work on that. That is good.

Ms. Castor, you are recognized for 5 minutes.

Ms. CASTOR. Thank you, Mr. Chairman, and thank you to all of you for helping us keep the 340B program strong and true to its original purpose.

The providers in my local community that are covered entities that participate are the ones that are providing inordinate amounts of charity care. Most of them never recoup the reimbursements that they need. For example, the St. Joseph's Children's Hospital Chronic Complex Clinic for medically fragile children—that is part of the BayCare Health System—behavioral health and substance abuse services at BayCare Behavioral Health and St. Joseph's Care Clinic that stretches the federal Ryan White funding to support a continuum of care to maintain a high retention rate of HIV patients.

Tampa General Hospital is our safety net hospital. They provide multi-million dollars in charity care though that is never recouped. So 340B has been a godsend to their mission in our community. Captain Pedley, HRSA has already audited a third of hospitals in the 340B program but only a small fraction of the drug manufacturers.

Program integrity is appropriate for all stakeholders. Can you please indicate your intention with regard to undertaking audits and ensuring compliance for the drug manufacturers?

Ms. PEDLEY. So we audit manufacturers every year. We have conducted seven audits thus far. We plan to conduct an additional five this year. As with——

Ms. CASTOR. What percentage is that?

Ms. PEDLEY. So there are 600 manufacturers—whatever that comes out to be.

Ms. CASTOR. What have the audits found so far?

Ms. PEDLEY. Thus far, we do post the audits on our website and we have not had any findings whereby the manufacturers are not

in compliance with the statute. The manufacturers have a more narrow focus than the 340B-covered and that is to provide the drug at or below the ceiling price and that is what we audit. But that is only one tool we use for manufacture compliance. We also ensure that once they are in the Medicaid program that they appropriately sign an agreement with HRSA to provide the drugs at or below the ceiling price.

We also issue regulation and guidance in the program related to manufacturer compliance. We also review all allegations that we receive if a covered entity is not receiving a price at or below the ceiling price and we investigate each of those situations.

Ms. CASTOR. And I think a lot of folks don't know that nearly one-third of the total of 340B discounts is due to a penalty that is enforced against drug manufacturers for raising the price of drugs higher than the rate of inflation or voluntarily providing a discount lower than the 340B price and that manufacturers could avoid the penalty by not increasing their drug prices at such high rates. How does that work?

Ms. PEDLEY. So the 340B ceiling price, again, it is in statute and it is informed by components reported under the Medicaid drug rebate program and that is the average manufacturer price and the unit rebate amount and we receive those components from CMS to calculate the price.

However, if the drug company does raise the price of their drugs higher than the rate of inflation there is a penalty that kicks in and that causes the 340B ceiling price to equal a zero. HRSA has policy in place and a final regulation that is effective October 1 that when that ceiling price equals a zero that the manufacturer charge a penny.

Ms. CASTOR. So that is a very important incentive and, again, helps keep the burden off the taxpayers that I think needs to be maintained as we move forward.

Captain Pedley, all the witnesses here—and you can hear the comments from the committee—said HRSA needs regulatory authority to properly administer 340B and I strongly favor appropriate HRSA oversight to ensure the highest level of program integrity. But HRSA's proposed Mega-Guidance last year would have dramatically limited the use of 340B well beyond congressional intent and harm many hospitals and their ability to provide charity care and the whole continuum of care. For example, it would have prohibited discharge prescriptions needed to prevent unnecessary readmissions, eliminated 340B in infusion centers for patients with no other options for cancer care, and created a complex and unworkable definition of who is a patient.

If the Congress provides HRSA with such regulatory authority, how can we be assured that harmful proposals such as these wouldn't go beyond the congressional intent?

Ms. PEDLEY. So HRSA's proposal in 2015 and the omnibus guidance we did address patient definition, and based on some of the things that we were seeing in our program integrity efforts such as audits informed our decisions around how to define certain elements in that guidance.

We did receive over 1,200 comments that we took into consideration very seriously in drafting a final guidance that was sent to

OMB in the fall but was then withdrawn. So we do take the stakeholders' comments very seriously.

Ms. CASTOR. To be continued. Thank you very much.

Mr. MURPHY. Dr. Burgess is not here so it will be Mrs. Brooks.

Mrs. Brooks, you are recognized for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman.

Captain Pedley, I would like to talk a bit about what it means for diversion to occur in the 340B program and how common is it for you to find evidence of diversion in your audits.

Ms. PEDLEY. So the statute states that 340B drugs can only go to an eligible patient but the statute does not further define what a patient is in the program.

So we have historically defined in guidance what it means to be a patient. We have guidance currently in place from 1996. We did attempt in 2015 in the proposed guidance to further clarify the definition of a patient and we do audit that information when we audit.

I don't have the specific numbers on findings for diversion and we can make sure to get those to you. But that is one of the areas that we specifically look at when we audit covered entities.

Mrs. BROOKS. Could you provide, though, some examples of diversion that you have found in audits?

Ms. PEDLEY. So an example may be that a covered entity sees a patient. That patient is also seen at an outside provider at their private practice, and if that patient comes back to the hospital, for example, to see that patient.

There may not have been sensitive enough systems in place to know where the drug was prescribed from because the private practice doctor, unless it was a referral arrangement, would not have been eligible for the program. So that is an example of an ineligible patient.

Mrs. BROOKS. And so that would be a finding against that hospital or provider?

Ms. PEDLEY. Correct.

Mrs. BROOKS. And then what happens? What happens next when you do have a finding like that?

Ms. PEDLEY. So when there is a finding of diversion, the statute does require that the covered entity offer repayment to the manufacturer. They are also required to submit a corrective action plan to HRSA which we review and approve and then monitor the covered entity to ensure that that corrective action plan is appropriately implemented. They do, again, have to offer the manufacturer repayment for any drugs that were diverted.

Mrs. BROOKS. And how long is the duration of a corrective action plan, typically?

Ms. PEDLEY. It varies on the covered entity type and how severe the issue was, for example, whether it was one issue of diversion or many issues of diversion. So it does depend on that.

But we do follow follow up with the entity and monitor them throughout the process.

Mrs. BROOKS. Do you have any recollection of what is probably one of the more egregious issues involving a corrective action findings in audits?

Ms. PEDLEY. So in terms of corrective action plans, we do assess. Many times it may be that they have to make corrections to their software systems that track eligible patients and they will have to adjust those accordingly. That is a common error that we will see.

Mrs. BROOKS. And so what steps would you say that HRSA takes to minimize the amount of diversion that occurs in a 340B drug pricing program?

Ms. PEDLEY. So I would say first and foremost we provide education to the covered entities regarding the definition of a patient, best practices in this space, and how to ensure against diversion. The covered entities have to annually recertify and attest to compliance with program requirements and then again through our audits we do ensure that there is no diversion. If there is diversion or any audit whereby there is repayment, we do consider those entities for reaudit so that we can go back and check to make sure the corrective action plan has been appropriately implemented and that not continuing.

Mrs. BROOKS. Have you ever terminated an entity?

Ms. PEDLEY. We have terminated one covered entity for not submitting a corrective action plan. We were able to terminate them through that mechanism. We have terminated contract pharmacies through the program where a covered entity was not providing oversight and there were a few cases where we terminated a child or offsite clinic of a hospital because they were not eligible for the program. But that is just through the audit process. We also terminate through our recertification process and some other quarterly integrity checks that we do to ensure compliance.

Mrs. BROOKS. And Ms. Bliss, can you please let us know what recommendations does OIG have to help reduce diversion? What recommendations have you made?

Ms. BLISS. We have recommended that the patient definition be clarified so that it is more clear which patients and which prescriptions in particular are eligible for the 340B discounted price.

We have also examined how covered entities work with their contract pharmacies and raise concerns that the covered entities themselves need to conduct additional oversight and independent audits of their contracted pharmacies to help ensure there is not diversion.

Mrs. BROOKS. Thank you. My time is up. I yield back.

Mr. MURPHY. OK. Mr. Tonko, you are recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair.

As we have heard today, the 340B program is a critical component of the safety net that serves our nation's most vulnerable patients. Congress created 340B drug discounts to enable these safety net providers to stretch scarce resources and provide comprehensive services to vulnerable patients. However, HHS's recent proposed rule calls for drastic cuts in Medicare payments to 340B hospitals. I am deeply concerned that these proposed cuts would greatly limit 340B hospitals' ability to provide vital services.

So Captain Pedley, can you elaborate on the types of services that 340B hospitals provide to vulnerable patients?

Ms. PEDLEY. So under the 340B program, they are able to purchase the drugs at a discount and, again, provide those drugs to

their patients. But beyond that, that would be outside of HRSA's authority regarding the other types of services that they provide.

Mr. TONKO. Yes. If the CMS rule is successful and results in certain safety net hospitals having less revenue, what impact might that have on their ability to provide services for low-income populations?

Ms. PEDLEY. It is a CMS rule and because it is going through the rulemaking process I am unable to comment because it is out for public comment.

Mr. TONKO. Anyone on the panel able to suggest what that impact would be?

Ms. DRAPER. No.

Ms. BLISS. Not in a measured way. The CMS rule is proposing to reduce Medicare Part B reimbursement for separately payable 340B drugs in the hospital outpatient setting. So it would potentially reduce the savings generated by the 340B discount. There are other proposed changes to payments through the outpatient prospective payment system included in that rule. So I don't have a way to say how that would net out.

Mr. TONKO. Yes.

Ms. DRAPER. We did conduct work in 2015, looking at the intersection of 340B and the Medicare Part B program and we did find that for DSH hospitals that their Part B spending on drugs was substantially higher than non-DSH hospitals—almost twice as much—and we found that it suggested prescribing patterns of providers perhaps prescribing more and more expensive drugs than 340B hospitals.

Mr. TONKO. Yes. The 340B discounts are also critical for disproportionate share hospitals which provide care to uninsured and under insured populations. A recent study found that 340B disproportionate share hospitals provided some \$23.7 billion of uncompensated care in 2014 alone.

So, Captain Pedley, the discounts provided through the 340B program are one reason why 340B hospitals are able to provide those services to patients who are under insured or uninsured. Is that your understanding?

Ms. PEDLEY. So the intent of the program was for the entities to purchase the drugs at a discount in order to stretch their resources. The statute is silent regarding whether the patient is insured or uninsured.

Mr. TONKO. But, obviously, it is going to help some in those categories?

Ms. PEDLEY. That was the intent of the program.

Mr. TONKO. Right. And GAO has previously found that for all the covered entities it reviewed, 340B savings, and I will quote, "allowed them to support their missions by maintaining services and lowering medication costs for patients," which is consistent with the purpose of the program.

So, Dr. Draper, can you elaborate on the ways entities use 340B revenue to maintain services?

Ms. DRAPER. Yes. We talked to a small number of covered entities when we did our 2011 work and, for example, some federally qualified health centers talked about perhaps expanding their number of sites to reach more patients and to expand their serv-

ices. So that was one example of how they use the money. But, again, the money is not specifically tracked so we don't know how much of that was used specifically for that but that is what they told us.

Mr. TONKO. Yes. Thank you.

And, Captain Pedley, I understand the proposed rule was issued by CMS and not HRSA. But is it fair to say that a drastic reduction in payments to 340B hospitals would have a significant impact on covered entities in your program?

Ms. PEDLEY. I am unable to comment due to the fact that it is in proposed format.

Mr. TONKO. Right. Well, thank you.

Mr. Chair, I am all for finding solutions to rising drug costs. But this proposed rule does nothing to address that. It would be a disaster for 340B hospitals and certainly for the critical services they provide.

With that, I yield back.

Mr. GRIFFITH. I thank the gentleman.

The gentleman from New York, Mr. Collins, is now recognized for 5 minutes.

Mr. COLLINS. Thank you, Mr. Chairman.

I want to thank the witnesses as well and maybe, to start with a summary, we all understand the importance of 340B including the pharmaceutical companies, what the intent was in 1992.

I think the reality is that the landscape of the cost of drugs, especially in the oncology world, especially as we have gotten into some of the biologics and the treatments, which are great for any and all of these patients. But the costs are astronomical. And as a result then these discounts become very significant and much more so than a generic drug type of thing.

So it has been a very changing pharmaceutical world, certainly the last 10 or 15 years compared to '92. I think all of us are worried about the transparency—clearly, the lack thereof. The definition of a covered patient—because none of us want to see this program implode unto itself. And I guess the example I use, if you are an airline and you are flying a plane with 200 seats and the average price on the plane is \$400 but you do know that you have got to discount 10 seats on that airplane. So you have got a revenue piece that gets into your pricing model that you have got 190 seats at \$400 and 10 seats at \$200, you got that model.

But what we are starting to see, especially in the oncology world, is private hospitals buying up oncology practices. There is only one reason they are buying the oncology practices. Those are the most expensive pharmaceutical drugs prescribed and a 50 percent discount on a \$60,000 drug is real money, and we don't know where the money is going. We don't know if the patients are getting it properly or whether there is a diversion.

But as that percentage goes up, think of the airplane taking off now with 200 seats and half of them are at \$400 and the other half are at a 50 percent discount. There is only one thing that is going to happen. The \$400 price is going to \$500. So here we are. We always are worried about the cost of pharmaceutical drugs but potential abuse in the 340B program—there is no free lunch in America. At least that is what we were taught growing up. The price of the

drugs will go up because the abuse results in the most expensive drugs grabbing this discount.

So the transparency is critical and I think our committee can work together on that. I do know factually there are hospitals that have a line item in their P&L and it is called 340B discounts. 340B discounts is an actual line item on their profit and loss statement and they don't use it for additional services. It is simply a line item on the P&L and that is where we need to know where the money is going.

These are not the grantees. The grantees, the Ryan White AIDS clinics, we know exactly what they are doing and that was the intent back in 1992. And some of the grantees are very worried—because I have met with them—that if we don't get this under control there could be impacts on them and nobody wants to impact any of the grantees.

So I guess it comes back, Captain Pedley—as we have heard the others, the OIG and the GAO state, we need this clarity on patient definition. We need clarity on requirements for transparency and we need perhaps clarity out of HRSA. What do you need from us? Because guidance is guidance. Regulations and regulatory authority is that.

But there seems to be almost a disconnect of what you are allowed to do, what you are not allowed to do. Do you need more regulatory authority for Congress or don't you? You see my worries and I hope—I tried to give you an example of why we have got to get this under control.

Ms. PEDLEY. Based on the court ruling in 2014, the court held that the statute only provides HRSA regulatory authority in three specific places and that is the ceiling price and civil monetary penalties for manufacturers and administrative dispute resolution process. The first two are combined.

All other areas of the program we do not have specific regulatory authority. We do propose in the fiscal year '18 president's budget to provide that regulatory authority for HRSA. Regulatory authority does provide us the ability to be more clear and the requirements of the program, which is why we did include that in the president's budget.

Mr. COLLINS. So are you saying right now—for instance, I also serve on the Health Subcommittee of Energy and Commerce—do we on the Health Subcommittee have the language you would like? Because I would think fairly quickly we could move that language into a bill and I think, in a bipartisan way, move that through Congress. Have they been that specific? Has HRSA been that specific?

Ms. PEDLEY. I would have to check with my department colleagues on whether there has been specific language.

Mr. COLLINS. If there is, could you provide that to the committee and to myself? Because I think that could be a very quick starting point.

Thank you, Mr. Chairman. I know my time is up. Thank you all for your testimony.

Mr. GRIFFITH. Thank you.

The gentleman from California, Mr. Ruiz, is recognized for 5 minutes.

Mr. RUIZ. Thank you, Mr. Chairman. Thank you for this conversation. I have worked very closely with FQHCs and rural clinics. In fact, my medical career—I grew up in an FQHC, essentially, that was a block from my house, that took care of farm workers and I have seen patients that go in that couldn't afford their medications, and the 340B program is very essential for a clinic to be able to provide lower cost or at least cover the uncompensated under insured patients' costs and expand their services. So this is something that we definitely need to strengthen and to get right. But we are not talking about the big picture here. Why are drugs so expensive to begin with? That is the common sense question.

This is another band-aid approach to figuring out how can we make medications more affordable. But we are really not addressing the elephant in the room, which is why are these medications so expensive and perhaps in addition to transparency for this program where we want information from FQHCs and people that are struggling to meet the needs of underserved communities we should also have transparency on the big pharmaceutical companies on their costs and their pricing and where are their moneys going to so that we can figure out how we can help protect patients and other entities who have the focus on providing care for our neediest patients throughout America and our middle class families who are under insured and who are still struggling to make ends meet.

So we need to protect this crucial program which allows thousands of entities across the country to provide lifesaving prescriptions and care for the most vulnerable in our communities. And we know that these providers operate on very narrow margins and this program allows them to stretch their money to serve more patients. For example, the Desert AIDS Project in my district has a Hepatitis C program through which patients have access to the medication to treat their disease that otherwise can be cost prohibitive. And I have seen day in and day out how not having access to the proper medication is devastating to the overall health of patients.

Ms. Bliss, you talk about transparency. If you were to have a wish list of what you want to know in transparency within these programs, what would that wish list be like and what is the number-one information that you would most advocate for in terms of transparency?

Ms. BLISS. Thank you.

In the current program as it stands, we are advocating for increased transparency in the ceiling prices and identifying which claims are subject to the 340B discount and that is because there are existing program rules around those features of the program. So coming from an oversight entity, our link is to those criteria. Where we advocate that there be new information, new guidance is where there are missing rules.

So at this point, we are focused on the program as it stands. But we would, in an environment with additional rules, then we would certainly recommend transparency go hand in hand with new requirements so that we would be able to tell whether the program is working as intended.

Mr. RUIZ. For example, what kind of transparency would you place on hospitals and clinics?

Ms. BLISS. Well, at this point, there are no reporting requirements, as Captain Pedley has described, about how those savings get spent. But there are also no requirements about how they should be spent. So if hospitals were to start reporting those today, we wouldn't have a measure to judge the success or the outcomes or whether they would meet program intent. So reporting requirements tied to actual program criteria and goals are what would be most effective.

Mr. RUIZ. What would be most helpful for you, Captain Pedley, in being able to enforce these in terms of transparency?

Ms. PEDLEY. So the statute is silent on the savings piece. But we did propose in the budget to work with Congress on ensuring that the program does benefit patients, especially those that are low-income uninsured. We are also working in terms of transparency, as mentioned, on the 340B ceiling prices. We are working on a system to provide those ceiling prices to the covered entities so that they can see the prices that they are to be charged.

Mr. RUIZ. Well, I certainly appreciate and would advocate fiercely in order to see those cost savings translated into real patient out-of-pocket savings. I do also know as well that some of those savings are used for other programs that are in dire need in those underserved communities. And so, I think that a combination of both are very wise for these entities who work under very strained under resourced conditions to provide an enormous amount of help for patients who actually need it.

So thank you very much for your efforts.

Mr. GRIFFITH. Gentleman yields back.

The gentleman from Michigan, Mr. Walberg, is recognized for 5 minutes.

Mr. WALBERG. I want to start by thanking the chairman for holding this hearing.

The 340B program assists some of the most needy patients in our communities, including those who receive their care at community health centers, hemophilia treatment centers, and HIV clinics. As the number of entities participating in the 340B program has quadrupled since 2011, we have learned of greater oversight challenges and we are hearing of those today. I am hopeful and expectant that this hearing will help us clearly identify those challenges as we seek to preserve and strengthen this 340B program. So it continues to truly meet needs.

Captain Pedley, I see that HRSA first began auditing covered entities in 2012, as recommended by a 2011 GAO report. As has been noted, HRSA has fewer than 30 staff devoted to oversight of the 340B program. So it is understandable that HRSA has conducted relatively few audits over the years when compared with the size of the program—51 audits in fiscal year 2012, building up to 200 audits in fiscal year 2016.

What concerns me is the high rate of noncompliance that HRSA uncovered in a very small sample size of the program. Based on the available data, HRSA found noncompliance in 63 percent of 2012 audits. In 2013, that number rose to 79 percent of audits showing noncompliance in 2014. Eighty-two percent of audits in 2015—that number dropped slightly to 78 percent. And finally, in 2016, of the

audits that have been completed so far, 66 percent show noncompliance. Those numbers are just staggering.

Can you explain to me how HRSA selects the entities it audits and why those numbers are so high?

Ms. PEDLEY. So HRSA determines the audits on two different models. The first is a risk-based approach whereby we factor in certain risk factors and then randomly select based on those risk factors. We then separately specifically target audit some of the entities either based on specific allegations we have received about the entities already being in noncompliance or information that we have that we are unable to resolve an issue with an entity. Then we may go in and target audit an entity already known with an issue. So the entities that we choose are already at higher risk.

Mr. WALBERG. Am I correct that the audits only cover small number of the drugs that an entity might purchase through participation in the 340B program rather than a full audit of all drug purchases by that entity?

Ms. PEDLEY. So we use the standard auditing process whereby we do sample based on a statistical methodology, a certain percentage of the drugs to ensure that they meet program requirements specific to diversion and duplicate discounts. However, we do review all other aspects of the program outside of the sample in addition to looking at their policies and procedures, interviewing staff, and looking at all other documents necessary to ensure that compliance beyond just the sample of drugs.

Mr. WALBERG. So even the small number of audits connected by HRSA only cover a fraction of that entity's participation in the program?

Ms. PEDLEY. So the sampling is specific to the diversion and duplicate discounts that we sample and that is a standard process used in auditing. But we look at the entire program to ensure compliance, policies and procedures, interviews, looking at their software systems and how they track drugs.

Mr. WALBERG. OK. Thank you.

Ms. Bliss, has the OIG considered whether the 340B program encourages the use of brand drugs and discourages the use of generic drugs?

Ms. BLISS. We have not studied that particular issue.

Mr. WALBERG. Is there any incentive to study that? An incentive to prescribe more drugs and more expensive drugs because the entity has received those drugs that reduce price?

Ms. BLISS. In theory, there is certainly financial incentives to maximize the spread and your payments and your reimbursements.

Mr. WALBERG. Ms. Bliss, has the OIG reviewed whether the 340B program has created an incentive for hospitals to acquire practices?

Ms. BLISS. We have not specifically examined hospital incentives. I believe my colleague from HRSA had some work touching upon that issue.

Ms. DRAPER. Yes.

Mr. WALBERG. Ms. Draper.

Ms. BLISS. Oh, I am sorry.

Ms. DRAPER. That is OK. Actually, in 2015 we did look at Medicare Part B, the intersection of that with the 340B program and

we did find the average number of oncology patients increased for all hospital groups but the most for the 340B DSH hospitals.

And we also found that the Part B drug spending was substantially higher at 340B DSH hospitals which suggests that the financial incentives may influence prescribing patterns to prescribe more and more expensive drugs.

Mr. WALBERG. OK. Thank you.

I yield back.

Mr. GRIFFITH. I thank the gentleman.

The gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you.

Well, I am happy to see that everyone on the committee has expressed their support—just about everybody—for the 340B program because it certainly is a vital source for health care providers that really underpins our safety net programs. And I am all in favor of doing everything we can to make sure that we provide the proper oversight. But I wanted to make a couple of comments. One may seem irrelevant but I would hope that members of this committee would have as great enthusiasm for audits of the Defense Department and where big money is really spent.

And I would also like to comment my support for and associate myself with the remarks of Dr. Ruiz, who was talking about hep C patients being able, under this program, to be able to afford drugs that could offer a cure, but that we also want to look at why the pharmaceutical companies are charging tens of thousands of dollars for this drug and charging so much for other drugs and I think that this committee needs to look at more than—this is really not, I don't think a discussion about the price of drugs as much it is a particular small program.

I am concerned with the CMS-proposed rule and I know, Captain Pedley, that you said it is under advisement and so you can't talk about it. But can you describe it so that I understand it better what this proposed rule would do? Because what it sounds to me is at the end of the day that the entities like hospitals and FQHCs would receive less money. Can you describe it?

Ms. PEDLEY. I don't know the details of that rule. That is under the purview of CMS and we could help connect you with them. But I would be unable to go into any detail.

Ms. SCHAKOWSKY. OK. And you were also asked the question describe the types of comprehensive services 340B covers. You were just strictly talking about the discount drugs. Is there anything else that you can add about that?

Ms. PEDLEY. HRSA does not track or have information on how the entities use the savings to provide or care to more patients.

Ms. SCHAKOWSKY. OK. The 340B program has a demonstrable effect in helping disproportionate share hospitals and rural hospitals save their patients and that is a key part of the program that they are able and actually required to spend that money into engaging in meaningful and beneficial work to support the most vulnerable.

So let me ask you then what you think are the key—Captain Pedley, the key areas that we ought to be looking at to support your work in making sure that your audits are as effective as they can be and that this program is as effective as it can be.

Ms. PEDLEY. As proposed in the fiscal year '18 president's budget, HRSA only, again, has regulatory authority in the three specific areas and we have proposed guidance in all other areas. The regulatory authority across the program is critical for us to be able to provide clarity in our program requirements and assist HRSA in our oversight efforts to be able to then enforce those requirements. So regulatory authority is key.

Ms. SCHAKOWSKY. So this program has just been described as a real mess by some others on the other side of the aisle. Dr. Draper, would you agree that that is accurate, based on what GAO has looked at?

Ms. DRAPER. Well, we have identified weaknesses in oversight and we believe that the oversight needs to be improved and there are things that can be undertaken to make that happen.

Ms. SCHAKOWSKY. What is the most important thing that we ought to do?

Ms. DRAPER. Well, we talked a little bit about—I want to reemphasize about hospital eligibility. I think it is really important to think about HRSA's role with oversight related to participating hospitals. In 2011, about a third of U.S. hospitals were participating in the 340B program and by 2015 they are 40 percent. HRSA may have more updated numbers.

But I think the issue, because other grantees have specific requirements based on their grants that they have to follow in treating under insured or uninsured patients, you have a range of hospitals participating in this program and they operate in settings that provide both inpatient and outpatient services.

So the risk for diversion is really—there is more risk. Because this is an outpatient program, drugs are not to be used for an inpatient setting. Hospitals also tend to have more complex contracting arrangements in organizational settings, which is really different than the federal grantees, and then they provide a larger volume of drugs in multiple settings. So I think the risk is probably higher for a hospital and that is why I think that the hospital eligibility criteria is really critical as well as the definition of a patient.

Ms. SCHAKOWSKY. In my home state of Illinois there are over a hundred hospitals participating in the 340B program, and by and large, I think, and I am not disagreeing that we want to look at this carefully, but that helps those institutions better serve their patients. The 340B program helped a 9-year-old patient with a brain tumor who receives care at the University of Illinois in Chicago and they were able to afford a drug that she needed for her chemotherapy regimen that is not covered by her insurance.

So, we all have anecdotal information, I think. But I just worry that we don't want to throw out the baby with the bath water.

Ms. Bliss, what would you say is the most important thing?

Ms. BLISS. Clear program rules are fundamental to ensuring program integrity, accountability, and even assessing to what degree the program is working.

Ms. SCHAKOWSKY. OK. I yield.

Mr. GRIFFITH. I appreciate that. Thank you very much for yielding back and I now recognize the gentlelady from California, Mrs. Walters.

Mrs. WALTERS. Thank you, Mr. Chairman, and I would like to thank the panelists for being here today.

Captain Pedley, I understand that the number of entity child sites has more than doubled in the past 6 years, rising from roughly 16,500 in 2011, according to GAO, to 41,132 as of yesterday, according to HRSA. Two weeks ago on July 5th, HRSA listed the number of registered child sites at 40,745. Yesterday, July 17th, that number had increased by almost 400 sites. That is a drastic increase in child sites. And I would like to get a sense of what is driving that increase in sites and how that affects program integrity. How much can this rise in child sites be attributed to consolidation—that is, the trend of larger entities often DSH hospitals find smaller clinics and physician practices that as a result fall under their 340B umbrella?

Ms. PEDLEY. The statute is very specific as to which entities are eligible for the program and HRSA's role through that process is to ensure that when an entity applies that they do meet the statutory requirements. So everyone that we do list in the program does meet the statutory requirements and is eligible.

Mrs. WALTERS. OK. When a covered entity acquires another practice as a child site, it is my understanding that the drugs dispensed to that child site's patients often becomes eligible for 340B discounts. Does that child site take on any new statutory or regulatory obligations such as providing the kind of care that originally qualified the parent site for 340B status?

Ms. PEDLEY. So specifically for a hospital, and it may be different for a grantee, but for a hospital if they do acquire an outpatient facility they do first have to be reimbursable on that hospital's Medicare cost report before they are eligible for the 340B program because that is our test to ensure that they are an integral part. Once they are in that cost report then they also have to enroll, be listed on our database. They can then purchase drugs at that clinic as well and they have to meet all other 340B requirements just as the main facility does.

Mrs. WALTERS. OK. And to what extent is consolidation guided by perverse incentives? For example, a recent report has shown that there has been a 172 percent increase in the consolidation of community oncology practices into hospitals since 2008.

Ms. PEDLEY. HRSA's role is to ensure that everyone that does register does meet statutory requirements. I am unable to speculate on business decisions a hospital may make to acquire those facilities. Our role is to ensure that they are eligible for the program.

Mrs. WALTERS. OK. And as you know, oncology drugs can be quite expensive, and I know we talked a little bit about this before. If the covered entity is purchasing oncology drugs at the 340B discount but not charging the patients at a discounted rate for those drugs, this can be profitable for the covered entity.

Does this function to serve vulnerable patient populations and, if not, does it run counter to the intent of the program and how does this consolidation affect patient care?

Ms. PEDLEY. The statute is only specific around the different compliance elements related to the 340B program—for example, the patient definition and duplicate discounts. It does not provide HRSA the authority around how the entity uses those savings.

Mrs. WALTERS. OK. And how does this consolidation affect patient care?

Ms. PEDLEY. I am unable to comment on those business decisions made by the hospital.

Mrs. WALTERS. OK. I yield back the balance of my time. Thank you.

Mr. MURPHY. Ms. Clarke, you are recognized for 5 minutes.

Ms. CLARKE. I thank you, Mr. Chairman, and I thank our panelists for enlightening us today with this discussion.

I have been an ardent supporter of the 340B program. In fact, I have six nonprofit safety net 340B hospitals as well as multiple federally qualified community health centers and clinics in my district. Having the access to affordable medications provided through this program has saved countless lives in my district as well as improved the quality of life for many of my constituents. It is due in large part to this program that one of the hospital systems in my district was able to increase uncompensated care by 34.68 percent.

With the current debate raging around the repeal of the ACA and my Republican colleagues' attempt to systemically dismantle the Medicaid program by their health care reform bills, the 340B program is needed now more than ever. However, I can't overlook numerous government reports citing the vulnerabilities in this program. Drug manufacturers have also expressed their concerns about the reports of such vulnerabilities.

To be clear, I support the intent of the program, but I do believe that more transparency and accountability is required. Therefore, additional oversight and reasonable checks and balances are needed to strengthen the program.

So my question is to you, Captain Pedley. The first question is can you provide me with the dates by which some of the oversight tools stemming from the GAO and OIG recommendations will be fully implemented? Specifically, what is the estimated completion date for the ceiling price website which can help ensure that covered entities are paying the appropriate drug price? And can you tell me the date by which a centralized mechanism similar to the 340B Medicaid exclusive file will be up and running for Medicaid managed care organizations?

Ms. PEDLEY. The 2011 study from GAO did recommend information for us but specific to the ceiling price system that you mentioned we received funding in fiscal year '14. We honored that and we had a contract put in place that September in order to start development of that system. It is complex. There are over 40,000 drugs as part of that system.

We also have to ensure that it is developed in a way to ensure the confidential and proprietary nature of those prices and to ensure that the information in that system is not redisclosed. We are getting close to the release of that system and plan for it to be released in the coming months so the covered entities are able to view the ceiling prices.

Ms. CLARKE. So that would be this year?

Ms. PEDLEY. In the coming months.

Ms. CLARKE. 2017. Coming months. Months are always coming. [Laughter.]

Ms. PEDLEY. We do hope that it is soon and we have an education plan in place to ensure that those that are going to be able to use the system have adequate time to learn it so they can understand more about that system and the information it will contain.

Ms. CLARKE. The 340B Medicaid exclusive file—is that part of the system that you are speaking of?

Ms. PEDLEY. No. That is a separate document—the Medicaid exclusion file. There is currently one in place for Medicaid fee for service and the purpose of that file is to ensure that states and manufacturers have the information necessary to prevent a duplicate discount in the program, meaning to prevent a 340B drug discount and a Medicaid rebate on the same drug and the file is used for that purpose. We are separately going through the process of developing policy around duplicate discounts and Medicaid managed care.

Amendments were added to the statute in 2010 that did include now Medicaid managed care under the duplicate discount provision. We proposed in our 2015 omnibus guidance policy related to that matter and we received comments.

We are also in discussion with CMS related to that as there will also have to be policy in place by CMS in the states in order to make that process work.

Ms. CLARKE. Well, that process is of interest to me since I have a significant portion of the recipients in my district are now in Medicaid managed care plans.

Are there no completion dates that are up and running and when can those dates be really confirmed for us?

Ms. PEDLEY. So we first have to address the policy matters as to how to handle duplicate discounts related to Medicaid managed care and we are working with the administration currently on next steps related to that policy.

And then from there we would develop some type of file or information that would be used to prevent those duplicate discounts.

Ms. CLARKE. Well, let me close by congratulating you because I know that HRSA has been working on this item for a while and I am happy to see them finally done.

I yield back, Mr. Chairman.

Mr. MURPHY. Thank you, Ms. Clarke.

I recognize the gentleman from Pennsylvania, Mr. Costello, for 5 minutes.

Mr. COSTELLO. Following up on Ms. Clarke's line of inquiry, Captain Pedley, do you agree that given that two-thirds of the more than 70 million Medicaid enrollees are in managed care that whatever policy changes you are proposing there would probably go further in terms of addressing the issue of duplicate discounts than anything else?

Ms. PEDLEY. So under Medicaid managed care we do have to first develop that policy for how duplicate discounts are to be prevented under Medicaid managed care and that involves many parties through the process. Our authority specifically over how an entity prevents those duplicate discounts. CMS would have to separately address this issue with the states and the Medicaid managed care organizations.

Mr. COSTELLO. Do you agree that the policy change can occur within the regulatory realm and that no legislative action will be required?

Ms. PEDLEY. HRSA does not have regulatory authority related to duplicate discounts.

Mr. COSTELLO. CMS?

Ms. PEDLEY. I do not know the answer.

Mr. COSTELLO. So at this point, you do not know, and I don't mean this to be an unfair question—you don't know whether this will require legislative action in order to address the policy change required in order to drill down and prevent duplicate discounts in the managed care realm?

Ms. PEDLEY. We have the authority to present guidance as we have presented in our proposed guidance. In order to regulate on this issue, we would need a legislative change.

Mr. COSTELLO. OK. Do you have an opinion on what policy is required or legislative change is required in order to address that?

Ms. PEDLEY. So in the fiscal year '18 proposed budget we did propose for broad regulatory in the program in order for HRSA to better clarify our policy and to ensure that those policies are enforceable.

Mr. COSTELLO. Shifting gears, this is in the testimony of Ms. Bliss, HRSA worked with CMS and with Congress to obtain any needed authority to share ceiling prices with state Medicaid agencies. Do you have sufficient statutory authority to carry out that recommendation of providing ceiling prices to state Medicaid agencies?

Ms. PEDLEY. The statute is very specific to allow HRSA to provide the ceiling prices to covered entities. Therefore, we would need a legislative change to provide that information to the states.

We are currently in discussion with CMS regarding some possible administrative options. But we would need up front a legislative—

Mr. COSTELLO. OK. So let us talk about that for a second. Let us assume that state Medicaid agencies have the ability to learn of the ceiling prices. Can you share for this subcommittee how that would positively impact the program integrity?

Ms. PEDLEY. So in terms of providing the ceiling prices to states, it would not address any issues around duplicate discounts under the 340B statute. The ceiling prices would be in place to help inform the prices being paid for those drugs so that the states could reimburse the covered entity according to CMS rules.

Mr. COSTELLO. Can you share with me if you were to use claims level methods to identify claims for 340B purchased drugs and HRSA's guidance were updated related to same, what would that do in terms of program integrity? Would it improve it?

Ms. PEDLEY. So claims level data as suggested by the OIG in their study would make transparent the specific 340B drugs that are being purchased in order to prevent duplicate discounts.

Mr. COSTELLO. Do you believe that there is an insufficient technology platform right now in order to provide the type of transparency and accountability in order to make sure that this program operates the way that it should?

Ms. PEDLEY. So related to the recommendation made by the OIG for HRSA to provide more clarity regarding Medicaid managed care and how to prevent duplicate discounts we have been working very closely with CMS and we have convened many of the stakeholders in this space regarding how a solution may play out to prevent duplicate discounts—

Mr. COSTELLO. Right.

Ms. PEDLEY [continuing]. And an IT solution is very important to that process.

Mr. COSTELLO. There are the clarity issues. The clarity issues, because there is ambiguity, people can interpret things differently and thus you have different results given the same set of facts.

The question I have is for the enforcement side of this, you are doing, I think, less than 1 percent of all of these 340B facilities get audited, right, because of a manpower issue.

If you have the right IT in place, a lot of that sort of speaks for itself, does it not? And so the question is really geared more towards the IT side of this and if you have the right IT platforms in—well, here is a question.

I know my time has expired. If you had the right IT platform, do you feel that you could perform more audits in the same amount of time or in the same—could you provide more audits in a given year if you had a better IT platform?

Ms. PEDLEY. We have not explored IT related to whether we could conduct more audits or not. But that is something that we could look into.

Mr. COSTELLO. Well, the IT would be on the side of the reporting, right?

My time is up. I yield back.

Mr. MURPHY. Mr. Carter, you are recognized for 5 minutes.

Mr. CARTER. Thank you, Mr. Chairman. I thank all of you for being here. This is an extremely interesting subject on a very important subject as well.

I am going to start with you, Dr. Pedley, and by the way, Mr. Chairman, she is a doctor. She had a PharmD degree as well as being a captain. I know that Dr. Draper mentioned earlier when she was asked a question about what could we do to improve the program she mentioned about the hospital eligibility. But one thing that I am concerned about is the patient eligibility. If I have heard to, Dr. Pedley, say once I've heard you say it 50 times during this hearing the statute is silent. The statute is silent.

What do we need to do to clarify patient eligibility? Do we need to do it legislatively or can you do it?

Ms. PEDLEY. So the statute is silent on what entities do with their savings. It is—it does, however, mention that it has to go to a patient and HRSA does have authority related to creating guidance on who is an eligible patient.

And we have done that. We have a guidance currently on what defines a patient from 1996 and we proposed in 2015 additional guidelines related to the definition of a patient.

However, we do not have regulatory authority to regulate on what—

Mr. CARTER. That comes from Congress? So we need to do that?

Ms. PEDLEY. We would need a legislative change.

Mr. CARTER. OK. Count on it.

I want to go to you, Dr. Draper, because something is very important to me and that is—and I know that Representative Collins mentioned this and it is just something that I want to get clarified here because I think that there is a lot more that goes on here than we recognize—a lot more ramifications, if you will, and that is the GAO has released a number of reports including the report in June of 2015 that said the financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals also raises concerns. You acknowledge that. You acknowledge that you have seen a tendency for more 340B drugs to be used in those hospitals that are eligible for this.

Not only does excess spending on Part B drugs increase the burden on both taxpayers and beneficiaries who finance the program through their premiums, it also has a direct financial effect on beneficiaries who are responsible for 20 percent of the Medicare payment for their Part B drugs. This is something that is very important. Throughout this hearing, I have heard, well, this isn't really talking about prescription drug costs. Well, it is really talking about prescription drug costs because I can assure you this is helping to increase prescription drug costs.

One of the things that you were asked by Representative Collins is about the incentive for hospitals to buy up physician practices in order to gain that authority or in order to gain that ability to have them participate in 340B programs. Is that something that you see happening?

Ms. DRAPER. On our 2015 work we did find that the average number of—I know there has been a lot of discussion about oncology practices in particular, but the number of oncology patients increased for all hospital groups but the most for 340B hospitals.

Mr. CARTER. Absolutely, and the less competition we have within the healthcare system the higher the prices are. So it is just a merry-go-round here.

I am not naive enough to believe that this is the worst administered program that we have in the federal government but I think it is an example of how a program that was set out with the best of intentions can mushroom into a program that is just out of control.

Listen, it is not just the pharmaceutical manufacturers who aren't making as much money as they will. If I have insurance and I am being charged through the 340B program, the hospital is making money off of me. They are making money off my insurance. They are causing me to have higher premiums in the end. It has just as much an impact on me as it has on anyone. Even though I have insurance, it is causing insurance to go up. It's causing prescription drug prices to go up. Hospitals are right when they say, we are in compliance. They are in compliance because what is compliance?

Nobody can really define what compliance is. They can point to just about any program that they have and many of them have fine programs that they are administering. But until we make sure that we are setting the record straight on what they are supposed to be doing with this, no one is going to be out of compliance. Not only that, but the repercussions when we do find someone who is out

of compliance there aren't even there—there aren't even any penalties there. You have said that over and over again.

There is one word that we can sum up prescription drug pricing, that we can sum up this program with, and that is transparency. We need transparency within prescription drug pricing. We need it here. We need it in the individual markets—transparency. Whatever happened to the ability to just buy directly from the pharmaceutical manufacturer?

Right now there has got to be all kind of discounts, and I apologize for getting on my soapbox here but I am telling you it is out of control. Until we have transparency, we are never going to get this under control.

This program is a good program but it lacks clarity and it lacks oversight, and we have got to do something about it.

Mr. Chairman, I yield back.

Mr. MURPHY. Gentleman from Virginia for 5 minutes.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. Thank you all for being here today to testify.

Let me start with Ms. Draper. By the way, it is always nice to have you here and always love it when I see the Medical College of Virginia listed in your bio.

Ms. DRAPER. Great school.

Mr. GRIFFITH. Great school. Yes, ma'am.

This metric for qualifying DSH hospitals is an inpatient measurement yet 340B is for outpatient drugs. So does it make sense for us to use an inpatient metric for an outpatient program?

Ms. DRAPER. Well, we do believe that that is one of the weaknesses of the DSH measure. The other is that it really—the formula is based on covered patients and that would be those covered by Medicare and Medicaid. So, there are weaknesses inherent in that measure.

Mr. GRIFFITH. That's just another one of the many stones you all have turned over and said, whoops, we can't see anything there.

Ms. DRAPER. Yes.

Mr. GRIFFITH. Yes. And what is the DSH threshold? Do you know?

Ms. DRAPER. Well, it ranges for different hospital types. For some hospitals, it is 8 percent—the DSH adjustment—and for others like the general DSH hospitals it is 11.75 percent. So that is another issue—whether or not that is an appropriate level or not and, again, that has been pretty consistent over time with the program.

So, whether that needs to be reassessed that would also be a question.

Mr. GRIFFITH. Yes, ma'am. Thank you so much.

Captain Pedley, earlier Ms. Draper referenced that prior to the shift or the change there were 1,300—and if I get the numbers wrong you all correct me—1,300 contract pharmacies with the various entities or hospitals and now there are 19,000, if I wrote it down correctly when you said that earlier.

I got all kinds of complicated questions on that that I have been given. But why the great expansion in the number of contract pharmacies? Is it just because we lifted the cap of one or how did that happen?

Ms. PEDLEY. The 340B statute is silent on how these covered entities dispense and get these drugs to their patients. We had understood that through state law entities were contracting with pharmacies. So in recognition of that, we did develop guidance in 2010 that stated if they were going to have these contract pharmacies they needed to ensure they were also complying with the statutory requirements of diversion and duplicate discounts and we audit that information on those contract pharmacies when we go in to audit a covered entity.

Mr. GRIFFITH. All right. I am going to get to that in a second. But I have also heard that the contract pharmacies are not only allowed to charge a dispensing fee but some of them ask for part of the savings on the drug. Is that correct or is that incorrect?

Ms. PEDLEY. I don't have the information on that. That's a business matter between the parties and their contract.

Mr. GRIFFITH. But it is not prohibited?

Ms. PEDLEY. It is not prohibited.

Mr. GRIFFITH. OK. Now, let us get back to the audits. You have asked the hospitals to do the audits of the contracting pharmacies. When you go in and you check on those, obviously, you don't have enough people to check on 19,000 individual contracts with the various providers to the various entities. So have you uncovered problems and if you do, do you suspend somebody? Do you suspend the pharmacy or do you suspend the entity if they are not doing the proper oversight of the contracting pharmacies?

Ms. PEDLEY. So we have audited now over 800 covered entities but it doesn't stop there. We also do conduct the audits within those of their contract pharmacies. So we have audited over 18,000 contract pharmacy arrangements related to those audits. We do ensure that the covered entity is providing oversight. We sample 340B drugs dispensed from those pharmacies to ensure that they have not been diverted or have a duplicate discount, and if we do find the entity is not providing oversight of those contract pharmacies we will remove the pharmacies from the program.

Mr. GRIFFITH. All right. Now, that raises an interesting issue. If you have done the audits, and you touched on 18,000 contract pharmacies, those audits didn't reveal to you if some of them were getting a split of the savings with the entity?

Ms. PEDLEY. That is a matter outside of our authority so we don't review it when we audit them.

Mr. GRIFFITH. OK. Would you like to have that authority? I mean, as long as we are going in to look at this, and it looks like it is a bipartisan way, should we give you that authority as well?

Ms. PEDLEY. We would be happy to work with Congress on a specific proposal.

Mr. GRIFFITH. I appreciate that very much. Yes, ma'am.

All right. I might be the last one up. I have got about 40 seconds left. Anybody have something that they really want to—

Mr. CARTER. I do. I do.

Mr. GRIFFITH. I yield to the gentleman from Georgia. Oh, OK. I yield to the gentleman from Georgia, though.

Mr. CARTER. Dr. Pedley, I just want to make sure and understand. Most of the problems that you see, are they with the contracting pharmacies? Is it not true that most of the hospitals dis-

pense these medications that are covered under 340B through their own providers, especially with oncology? I mean, they dispense them out of the office.

Ms. PEDLEY. It is a combination of their in-house pharmacy and whether they contract with pharmacies. I think, as you mentioned, it also depends on the types of drugs. But it is a combination of both.

Mr. CARTER. Thank you. I yield back.

Mr. MURPHY. I yield back to myself. OK.

That being done, we are finished with the regular committee members. We have Mr. Welch, who, I assume, by unanimous consent, is allowed to participate today.

So I recognize the gentleman from Vermont, Mr. Welch, for 5 minutes.

Mr. WELCH. Thank you, Mr. Chairman, I appreciate it, and I thank the panel.

A couple of things. One, Mr. Chairman, with respect to transparency, I am all on board. We need that across the board. Number two, with respect to whatever auditing has to be done in order to get our hands around this program, I am all for that and I think you are doing a good job.

But I want to bring this back to what this means to rural Vermont and I think rural America. We are talking about the audit as though these nonprofit hospitals, like North Country Hospital in Newport, Vermont, is playing some kind of game and that just ain't the case. Folks there in a hospital are working hard, not making a lot of money, and are the vital community institution in Newport, Vermont.

And I know, Mr. Chairman, you have got that and, Mr. Carter, I know you have that as well. They are focused on trying to get costs down. That is their focus, and that cost going down means that they can serve other people in this rural and pretty poor community.

The pharma companies, frankly, are focused on shareholder profit. That is their job. But there is a tug of war here, and whatever it is we do—transparency, better audits—I do not want to compromise the ability of those rural community hospitals to do the job and get the services out to folks, and that has got to be the bottom line. For me, that is the bottom line. Rural America is getting hammered and it is not just Vermont.

The other issue, Mr. Griffith, you and I worked on to some extent—the 340B issue where these orphan drugs get mislabeled and the pharmaceutical companies take advantage of the fact that there is an orphan designation for a small component of what the use of that drug is and then they get the higher price on everything—and I would hope that would be part of it.

But just let me tell you about the North Country Hospital. If we lost the 340B designation, that would be \$2.7 million a year. That is what would happen to them. When Porter Hospital in Middlebury, Vermont—the nearest other hospital is about 40 miles away—when the orphan drug rule change was made that cost them \$500,000. That is big money in a rural community hospital.

So that is the focus here—I think ultimately at the end of the day whatever we do in transparency and on the audit and oversight, the bottom line for me is those community hospitals.

Commander Pedley, I do want to ask you about some of the challenges that you face in regulating in this area and share your best understanding of what you believe Congress intended when it enacted the provision on 340B.

Ms. PEDLEY. In terms of regulatory authority, due to the district court ruling in 2014, the courts did hold that we only have explicit authority in three areas: that is related to the ceiling price, civil monetary penalties for manufacturers, and the administrative dispute resolution process.

But we do not have that authority for all other areas of the program. We have developed guidance in those areas but we did propose in the budget to provide comprehensive regulatory authority for HRSA to oversee around.

Mr. WELCH. All right. Now, on the current application of the exclusion that has an effect on access to products in the 340B, is that something you have the ability to track?

Ms. PEDLEY. I am sorry. Did you say orphan drugs?

Mr. WELCH. Yes.

Ms. PEDLEY. So related to orphan drugs, there was an amendment in the statute in 2010 that the newly eligible hospitals, mainly, rural hospitals, are unable to purchase orphan drugs under the program at the 340B discount.

There was a lawsuit involving HRSA's interpretation related to that matter. Currently, under the program the policy is that the manufacturer does not have to provide the 340B discount to those newly eligible hospitals for drug—

Mr. WELCH. All right. Thank you.

Ms. Draper, it is very nice to see you. Thank you.

On the orphan drug issue, and the specific question of how many drugs have been recently pulled out of the program, is that something the GAO has reviewed?

Ms. DRAPER. We have not reviewed that.

Mr. WELCH. That information would be helpful and important, given the anecdotal evidence about real access. Is that something you would agree with?

Ms. DRAPER. I think anything that would help improve the transparency and integrity of the program would be good.

Mr. WELCH. OK. Thank you.

I thank the panel. Mr. Chairman, thank you for allowing me to participate.

Mr. MURPHY. Thank you very much.

That concludes this committee hearing. I would like to thank all the witnesses and members who have participated in today's hearing.

I would remind members that they have 10 business days to submit questions for the record, and I ask that the witnesses all agree to respond promptly to those questions.

Hearing nothing else, the committee is adjourned.

[Whereupon, at 12:31 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]



U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

July 14, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Examining HRSA’s Oversight of the 340B Drug Pricing Program.”

The Subcommittee on Oversight and Investigations will hold a hearing on Tuesday, July 18, 2017, at 10:15 a.m. in 2322 Rayburn House Office Building. The hearing is entitled “Examining HRSA’s Oversight of the 340B Drug Pricing Program.” An agency within the U.S. Department of Health and Human Services (HHS), the Health Resources and Services Administration (HRSA), oversees the program. The purpose of the hearing is to review HRSA’s oversight of the 340B Drug Pricing Program, as well as how the program is impacting patients, providers, manufacturers, and other stakeholders. Further, the hearing will examine potential areas for improvement within the program to ensure program integrity.

I. WITNESSES

- Krista M. Pedley, PharmD, MS, CDR, USPHS, Director, Office of Pharmacy Affairs, Health Resources and Services Administration, U.S. Department of Health and Human Services;
- Debbie Draper, Director, Health Care, Government Accountability Office; and,
- Erin Bliss, Assistant Inspector General, Office of Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services.

II. BACKGROUND

a. Overview of the 340B Program

The 340B drug discount program was created by Congress in 1992. The 340B program mandates that drug manufacturers provide outpatient drugs to eligible health care organizations (also known as “covered entities”) at reduced prices in order to remain eligible for reimbursements through entitlement programs such as Medicaid and Medicare. Covered entities include hospitals owned or operated by state or local governments that serve a higher percentage of Medicaid beneficiaries, as well as federal grantees such as federally qualified health centers (FQHC), FQHC look-alikes, family planning clinics, state-operated AIDS drug assistance programs, Ryan White CARE Act grantees, family planning and sexually transmitted disease

Majority Memorandum for July 18, 2017, Subcommittee on Oversight and Investigations Hearing
Page 2

clinics, and others, as identified in the Public Health Services Act (PHSA). The Health Resources and Services Administration, under HHS, is tasked with accepting applications and overseeing covered entities.

Citing a Committee report from the time the authorizing legislation passed, HRSA states that the purpose of the 340B program is to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹

Participation in the 340B program is voluntary for covered entities and drug manufacturers, but there are strong incentives to participate. Covered entities are eligible to receive discounts on outpatient prescription drugs from participating manufacturers. Covered entities report saving between 25 and 50 percent of the average wholesale price for covered outpatient drugs.² HRSA estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in fiscal year (FY) 2013,³ and \$4.5 billion in FY 2014.⁴ As of October 2016, 12,148 covered entities were participating in the program⁵ and roughly 1,200 pharmaceutical manufacturers participate in the program.⁶

Covered entities do not receive discounts on *inpatient* drugs under the 340B program, but can realize substantial savings through 340B price discounts and generate 340B revenue by selling 340B drugs at a higher price than the discounted price at which the covered entity obtained the drug. Moreover, while covered entities are prohibited from diverting any drug purchased at a 340B price to an individual who does not meet HRSA’s current definition of a patient,⁷ these entities are permitted to use drugs purchased at the 340B price for all individuals who meet the definition of a patient, whether or not they are low income, uninsured, or underinsured.

The 340B price for a drug paid by covered entities—sometimes referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug

¹ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program*, available at <https://www.hrsa.gov/opa/>.

² 340B Prime Vendor Program, *340B Price/Covered Outpatient Drugs*, available at <https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>.

³ *Examining the 340B Drug Discount Program: Hearing Before the H. Comm. on Energy & Commerce*, 114th Cong. (March 24, 2015) (statement of Diana Espinosa, Deputy Administrator, Health Resources and Services Administration).

⁴ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2017*, available at <https://www.hrsa.gov/about/budget/budgetjustification2017.pdf>.

⁵ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

⁶ There are 1204 manufacturers are listed by HRSA, 706 of which are deemed “active.” See Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Office of Pharmacy Affairs 340B Database*, available at <https://opanet.hrsa.gov/OPA/Manufacturers.aspx>.

⁷ For current definition of a patient, see HRSA’s website. Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *Eligibility & Registration*, available at <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

Majority Memorandum for July 18, 2017, Subcommittee on Oversight and Investigations Hearing
Page 3

manufacturer may charge covered entities.⁸ Manufacturers are permitted to audit covered entity records if they suspect product diversion or multiple discounts are taking place. Occasionally, the formula results in a negative price for a 340B drug. In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—referred to as HRSA’s penny pricing policy.

In March 2010, HRSA issued guidance allowing all covered entities—including those that have an in-house pharmacy—to contract with multiple outside pharmacies, referred to as contract pharmacies. Prior to 2010, covered entities were allowed to contract with only one pharmacy—either an in-house pharmacy, or an individual contract pharmacy.⁹ The growth and oversight of contract pharmacies since 2010 has been identified as an issue of concern by the Office of Inspector General of the U.S. Department of Health and Human Services (HHS OIG), and the U.S. Government Accountability Office (GAO) is planning an upcoming report examining that issue.

Many 340B program covered entity parent organizations have multiple associated “child sites.” Child sites can include satellite clinics or facilities, hospital departments, outpatient treatment units, and other facilities. Child sites are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on a hospital’s most recently filed Medicare cost report. As of July 5, 2017, 40,745 covered entity sites were participating in the 340B Program, including 17,965 disproportionate share hospital (DSH) sites.¹⁰

Hospitals’ participation in the 340B program has grown markedly in recent years—faster than that of federal grantees, increasing almost three-fold in the number of participants from 2005 to 2011.¹¹ According to a 2011 report by the GAO, a third of all hospitals participated in the program, and DSH hospitals alone represented about 75 percent of all 340B drug purchases.¹² Currently, approximately 40 percent of all U.S. hospitals participate in the 340B program. According to HRSA’s database on covered entities, as of July 5, 2017, DSH hospitals accounted for 44 percent of covered entities sites.¹³

⁸ Manufacturers may sell a drug at a price that is lower than the ceiling price, so covered entities may negotiate prices below the ceiling price. The discount is determined by dividing the average total Medicaid rebate percentage of 15.1% for single source and innovator multiple source drugs, and 11% for non-innovator multiple source drugs by the average manufacturer price (AMP) for each dose and strength. The Medicaid statute defines AMP as the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers are required to report AMP and their best price to the Secretary, but subject to verification, manufacturers calculate the maximum price (“ceiling price”) they may charge 340B entities.

⁹ 75 Fed. Reg. 10272, 10274–10278 (March 5, 2010).

¹⁰ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

¹¹ U.S. Gov’t Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).

¹² *Id.*

¹³ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

b. Changes PPACA Made to the 340B Program

Enacted in 2010, the Patient Protection and Affordable Care Act (PPACA) made a number of notable changes to the 340B program, some of which have yet to be fully implemented.

- *Expanded Participation in 340B Program:*¹⁴ PPACA added the following to the list of covered entities entitled to discounted drug prices under the 340B program: (1) certain children's and free-standing cancer hospitals excluded from the Medicare prospective payment system; (2) critical access hospitals; and (3) certain rural referral centers and sole community hospitals. These 340B-eligible facilities also must meet other specified 340B participation requirements.
- *Changes to 340B Program Integrity:* PPACA required the Secretary of HHS to develop systems to improve manufacturer and covered entity compliance and program integrity activities, as well as administrative procedures to resolve disputes. The compliance and program integrity systems were to include a number of specifications to increase transparency and strengthen monitoring, oversight, and investigation of the prices that manufacturers charge covered entities, as well as additional improvements to ensure covered entities do not divert drugs or obtain multiple discounts. The Secretary was required to establish a new administrative dispute resolution process to mediate and resolve covered entity overpayment claims and manufacturer claims against covered entities for drug diversion or multiple discounts. Civil money penalty (CMP) sanctions up to \$5,000 per instance for manufacturer overcharges were authorized. The Secretary was required to establish standards and issue regulations for assessing CMPs on drug manufacturers for overcharge violations and was required to issue regulations to implement a dispute resolution process by which covered entities can report instances where they suspect they have been overcharged.
- *Required Manufacturers Communicate Prices to HHS:* PPACA required that pricing agreements stipulate that drug makers will report to the Secretary the quarterly ceiling prices for each covered drug and to offer these drugs to covered entities at or below these prices.

c. GAO and HHS OIG Findings

- *2011 GAO Findings:* In 2011, GAO issued a report, "Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement."¹⁵ GAO found that the 340B program allows certain providers within the U.S. health care safety net to stretch federal resources to reach more eligible patients and provide more comprehensive services. However, GAO cautioned that HRSA's then-current approach to oversight did not ensure 340B program integrity, and raised concerns that this

¹⁴ Section 7101, as amended by HCERA Sec. 2302, amended PHSA Sec. 340B.

¹⁵ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011).

vulnerability may be exacerbated by changes within the program. Among GAO's key findings:

- According to HRSA, the agency largely relies on participants' self-policing to ensure compliance with program requirements, and has never conducted an audit of covered entities or drug manufacturers.
- HRSA has not always provided covered entities and drug manufacturers with guidance that includes the necessary specificity on how to comply with program requirements, so participants may be interpreting guidance in ways that are inconsistent with the agency's intent.
- Participants have little incentive to comply with program requirements, because few have faced sanctions for non-compliance.
- With the program's expansion, program integrity issues may take on even greater significance unless effective mechanisms to monitor and address program violations, as well as more specific guidance, are put in place.
- PPACA outlined a number of provisions that, if fully implemented, would help improve many of the 340B program integrity issues identified.
- GAO identified other program integrity issues that HRSA should also address: (1) HRSA is not required to audit covered entities or further specify the agency's definition of a 340B patient; (2) HRSA does not plan to make any changes to or further specify its related nondiscrimination guidance; (3) HRSA guidance may allow some ineligible entities to be eligible for the program.
- Finally, GAO noted that while HRSA would benefit from more resources, limited resources could be prioritized to address areas of greatest risk to the program.

HRSA has addressed some of the concerns raised by GAO. For example, HRSA began conducting audits of covered entities and issued more specific nondiscrimination guidance for cases in which distribution of drugs is restricted.

- *2014 HHS OIG Findings:* Covered entities participating in the 340B Program may contract with pharmacies to dispense drugs purchased through the program on their behalf.¹⁶ Such pharmacies are referred to as "contract pharmacies." In a 2014 report examining "Contract Pharmacy Arrangements in the 340B program," HHS OIG noted that in 2010, the percentage of all covered entities that use contract pharmacies had risen

¹⁶ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Contract Pharmacy Services*, available at <http://www.hrsa.gov/opa/implementation/contract/index.html>.

from 10 percent to 22 percent.¹⁷ Moreover, the number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent. Some of HHS OIG's key findings were:

- HHS OIG found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways.
- In some cases, HHS OIG explained that different methods lead to differing determinations of 340B eligibility across covered entities. That is, two covered entities may categorize similar types of prescriptions differently. As a result, HHS OIG concluded "there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible."
- Several covered entities did not offer the discounted 340B price to uninsured patients at their contract pharmacies.
- Most covered entities examined did not conduct all of the oversight activities recommended by HRSA. Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance.
- Contract pharmacy administrators reported difficulties in identifying beneficiaries covered by managed care organization Medicaid, and some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts.

In June 2011, HHS OIG published a review of states' reimbursement policies and oversight related to 340B-purchased drugs. At the time, HHS OIG found that states lacked pricing information needed for oversight and that nearly half of states did not have written 340B policies.¹⁸

- *2015 GAO Findings:* In 2015, GAO issued a report, "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals."¹⁹ The report identified the characteristics of 340B DSH hospitals as compared to non-340B hospitals, and found that hospitals participating in the 340B program have a financial incentive to prescribe

¹⁷ Office of Inspector General, U.S. Dep't of Health and Human Services, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 4, 2014), available at <http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf>.

¹⁸ Office of Inspector General, U.S. Dep't of Health and Human Services, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321 (June 2011), available at <http://oig.hhs.gov/oei/reports/oei-05-09-00321.pdf>.

¹⁹ U.S. Gov't Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), available at <https://www.gao.gov/products/GAO-15-442>.

more drugs, and more expensive drugs to Medicare beneficiaries. Among GAO's key findings:

- 340B DSH hospitals tended to be larger in terms of facility revenues, and were more likely to be major teaching hospitals compared to non-340B hospitals.
- 340B DSH hospitals generally provided more charity care, and generally had DSH median adjustment percentages between two and three times larger than non-340B DSH hospitals, depending on teaching status.
- While most 340B DSH hospitals provided more charity care than non-340B hospitals, GAO found that 12 percent of 340B DSH hospitals studied were among those that provided the lowest amount of charity care.
- 340B DSH hospitals had higher Medicare margins, had substantially higher Medicare Part B spending per beneficiary (by 240 percent and 232 percent compared to non-340B DSH and non-340B institutions), and these differences were not attributable to differences in the health of the populations they served.
- The Centers for Medicare and Medicaid Services (CMS) uses a statutorily defined formula to pay hospitals for drugs, regardless of the cost to the hospital in purchasing those drugs.
- The 340B statute does not prohibit 340B entities from prescribing 340B discounted drugs to Medicare Part B beneficiaries, so HRSA and CMS have limited ability to hinder the 340B DSH hospitals' incentive to prescribe more, and more expensive drugs to Medicare beneficiaries.

III. CURRENT ISSUES

a. Program Growth Exceeds HRSA's Oversight Capabilities

For most of its existence, the 340B Program has not been subject to rigorous oversight. HRSA had 24 full-time employees (FTEs) for the 340B program in FY 2016, which it reduced to 22 FTEs for FY 2017 and 2018.²⁰ After GAO issued a 2011 report critical of the program's oversight, HRSA received additional funding of \$6 million in FY 2014 to increase its oversight efforts.²¹ However, the PPACA dramatically increased the size and scope of this program by expanding eligibility to more categories of hospitals, so the periodic audits conducted by the

²⁰ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²¹ In FY 2016 and FY 2017 HRSA budget was \$10.543 billion and \$10.401 billion respectively. For FY 2018, HRSA has requested \$9.9 billion. Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

Majority Memorandum for July 18, 2017, Subcommittee on Oversight and Investigations Hearing
Page 8

GAO and HHS OIG, and HRSA's own limited oversight may not be sufficient to conduct adequate oversight of this program.

The number of participating unique covered entities has grown from 3,200 in 2011,²² to 11,180 in February 2015, to 12,148 covered entities in October 2016.²³ The number of hospitals in particular has grown significantly, from 591 in 2005, to 1,673 in 2011, to 2,871 as of July 2017. The number of child sites has also grown dramatically. In 2011, GAO reported that the number of child sites had nearly doubled over the previous decade, reaching just over 16,500 registered sites.²⁴ According to HRSA, that number had reached 37,496 in October 2016,²⁵ and 40,745 registered sites by July 2017.²⁶

In addition to an increase in child sites, the number of contract pharmacies has grown greatly since HRSA issued its 2010 guidance on contract pharmacies. In 2011, GAO reported that while HRSA did not track individual contract pharmacies in use, there were more than 7,000 contract pharmacy arrangements through the program.²⁷ In its 2018 Budget Justification, HRSA reported that twenty-seven percent of covered entity sites have contract pharmacy arrangements, resulting in approximately 18,078 unique pharmacy locations.²⁸ The GAO has ongoing work that will examine the growth of contract pharmacy arrangements.

Finally, the amount that covered entities save on 340B drugs has also increased. In FY 2013, HRSA estimated that covered entities saved \$3.8 billion on drug expenditures.²⁹ In FY 2014, that estimate rose to \$4.5 billion in savings.³⁰

Despite the rapid growth of the program, HRSA's auditing has remained at or below 200 annual audits of covered entities since 2012, when HRSA's practice of auditing covered entities began. The next section covers the results of those audits.

²² U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²³ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁴ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²⁵ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁶ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Covered Entities*, available at <https://datawarehouse.hrsa.gov/topics/HealthcareSystems/CE340BDataExplorer.aspx>.

²⁷ U.S. Gov't Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011), <http://gao.gov/assets/330/323702.pdf>.

²⁸ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2018*, available at <https://www.hrsa.gov/about/budget/budgetjustification2018.pdf>.

²⁹ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Justifications of Estimates for Appropriations Committees—Fiscal Year 2016*, available at <https://www.hrsa.gov/about/budget/budgetjustification2016.pdf>.

³⁰ *Id.*

b. HRSA's Oversight Reveals High Levels of Non-compliance

HRSA's annual audits uncover a high level of non-compliance by covered entities. The HRSA audits from FY 2012 to FY 2016 demonstrate that non-complying entities violate program requirements in at least one of three ways: duplicate discounts, diversion to ineligible patients and facilities, and incorrect database reporting.³¹

Figure 1: Program Requirement Violations:

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
Duplicate Discounts	18	24	23	47	42
Drug Diversion	16	51	54	94	78
Incorrect Database	15	46	51	100	57
No Adverse Findings	19	20	18	43	59
Total Audits	*51	*94	*99	*200	*175

*Note: numbers do not sum because several entities had more than one type of violation.

c. Duplicate Discounts

Covered entities are prohibited from receiving duplicate discounts.³² A duplicate discount occurs when a covered entity receives a 340B discount on drugs provided to Medicaid patients *and* the state Medicaid agency also receives a rebate for the drug dispensed to the Medicaid beneficiary through the Medicaid Drug Rebate Program. When an entity enrolls in the 340B Program, it must determine whether it will "carve-in" or "carve-out" for Medicaid prescriptions. Entities that "carve-in" agree to buy Medicaid drugs through the 340B program without seeking a Medicaid rebate, while entities that "carve-out" agree to buy Medicaid drugs through the Medicaid Drug Rebate Program or otherwise. Duplicate discounts occur because there is overlap in eligibility for the Medicaid rebate and 340B programs. While Medicaid rebates benefit state Medicaid programs and 340B programs benefit 340B-covered entities, both of these programs target the same safety-net population.³³ The significant overlap in prescription eligibility makes discount errors likely, and HRSA's audits found duplicate discounts to be quite common. Further, 340B discounts are often determined retrospectively, which can also increase the rate of discount errors. At least 23 percent of 340B-covered entities audited had duplicate discount errors each year, as shown above in Figure 1.

In 2013, HRSA created the 340B Medicaid Exclusion File (MEF) as a strategy to prevent duplicate discounts for drugs subject to both Medicaid rebates and 340B prices for Fee-For-

³¹ Duplicate discounts, diversion, and incorrect reporting will be discussed later in this section.

³² Public Health Service Act, 42 U.S.C. 256b(a)(5)(A)(i).

³³ Jason Hardaway, *340B Program Puts Manufacturers At Risk of Duplicate Drug Discounts*, 41 PHARMACY AND THERAPEUTICS 1, 38 (2016).

Majority Memorandum for July 18, 2017, Subcommittee on Oversight and Investigations Hearing
Page 10

Service claims.³⁴ The MEF is a list of Medicaid provider number or national provider numbers (NPI) of each entity that has agreed to purchase all drugs billed to Medicaid through the 340B program. The MEF is intended to prevent duplicate discounts by notifying states and manufacturers which drugs are not eligible for Medicaid rebates. This measure counts on the integrity and continued participation of covered entities to disclose accurate and current information.

HRSA lacks a centralized mechanism similar to the MEF to prevent duplicate discounts for Medicaid Managed Care Organizations (MCOs).³⁵ This is a significant problem because an increasing number of Medicaid programs rely on Managed Care. In 2014, 76 percent of Medicaid enrollees were in some type of managed care.³⁶ The HHS OIG released a report in June 2016, finding that duplicate discounts are a severe issue for Medicaid MCOs. The data that most states collect for MCO drugs is not granular enough to detect all individual drug claims. Many states still used the MEF for MCO drugs, despite HRSA's guidance to develop alternate strategies, since the MEF only works for Fee-For-Service drugs. Duplicate discounts for MCOs participating in the Medicaid Drug Rebate Program is a relatively new problem. Prior to the PPACA, only Medicaid Fee-For-Service (FFS) claims were eligible for rebates. Unfortunately, the PPACA did not anticipate the issues involved with reconciling duplicate discounts for MCOs, which notoriously under-report Medicaid data to the states.

d. Diversion

HRSA prohibits the resale or transfer of 340B drugs to ineligible patients, known as diversion. Only individuals who are patients of 340B-covered entities are eligible for drug pricing discounts.³⁷ To be considered a patient of a covered entity, the individual must maintain his or her records with the covered entity, and receive health care services from providers employed by the covered entity.³⁸

In FY 2012, FY 2015, and FY 2016, close to half of HRSA's audited entities diverted benefits to ineligible patients – 31 percent of covered entities in FY 2012, 47 percent of covered entities in FY 2015, and 44 percent of covered entities in FY 2016 were found to have diverted drugs. Diversion violations reached a 54 percent high in FY 2014 and FY 2015, when over 50 audited entities offered drug pricing benefits to ineligible patients.

³⁴ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Notice: Clarification on use of the Medicaid Exclusion File*, Release No. 2014-1, 3 (Dec. 2014).

³⁵ 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52300, 52309 (Aug. 2015); See Office of Inspector General, U.S. Dep't of Health and Human Services, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430 (June 2016).

³⁶ *Medicaid Managed Care Enrollment and Program Characteristics, 2014*, Centers for Medicare and Medicaid Services, available at <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/medicaid-managed-care/downloads/2014-medicaid-managed-care-enrollment-report.pdf>.

³⁷ There is one exception: individuals registered in state-operated or funded AIDS Drug Assistance Program who are automatically eligible for 340B benefits. See 340B Prime Vendor Program, *Patient Definition*, available at <https://www.340bpvp.com/resource-center/faqs/patient-definition/>.

³⁸ See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 207 (Oct. 24, 1996).

The lack of a clear definition of “patient” sheds light on the high number of covered entities who committed diversion violations. HRSA’s definition of “patient” has been criticized widely for its vagueness. The HHS OIG has stated that “[there is] a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements.”³⁹ The GAO has also offered criticism, explaining that “HRSA’s current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B.”⁴⁰

To identify which 340B-eligible patients received prescriptions, contract pharmacies⁴¹ often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In its 2014 report, HHS OIG found wide variation in these eligibility determinations. Depending on the interpretation of HRSA’s patient definition, some 340B provider eligibility determinations would be considered diversion and others would not.⁴²

e. Incorrect Reporting

The administration of the 340B program depends on accurate database information. HRSA audits reveal that many covered entities are not fulfilling their obligations of maintaining current database information. With the exception of FY 2012, at least half of the audited entities kept incorrect records all other years, as shown above in Figure 1. The audits show that many times, records include clinic locations or outpatient facilities that are no longer in service. Another common error is that entities include unauthorized facilities in their database.

HHS OIG investigators have warned that incorrect reporting is one way to hide intentional abuses of government programs. Entities seeking reimbursement from Medicaid and Medicare sometimes practice poor bookkeeping to prevent auditors from noticing trends and practices that may alert the auditor to wrongdoing. As a result, it is imperative for program integrity that the covered entities be required to keep detailed records.

f. Unclear Program Requirements and Lack of Transparency Hamper HRSA’s Oversight Capabilities

In addition to significant growth, unclear program requirements and lack of transparency surrounding the program hamper HRSA’s ability to conduct sufficient oversight. According to a committee report from the time the authorizing legislation was passed, the purpose of the 340B program is to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”⁴³ However, neither the 340B statute nor

³⁹ Office of Inspector General, U.S. Dep’t of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).

⁴⁰ Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

⁴¹ Covered entities may contract with pharmacies to dispense drugs purchased through the program on their behalf. Such pharmacies are referred to as contract pharmacies.

⁴² Office of Inspector General, U.S. Dep’t of Health and Human Services, *Memorandum report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014).

⁴³ Health Resources and Services Administration, U.S. Dep’t of Health and Human Services, *340B Drug Pricing Program*, available at <https://www.hrsa.gov/opa/>.

Majority Memorandum for July 18, 2017, Subcommittee on Oversight and Investigations Hearing
Page 12

HRSA guidance explain how 340B providers must use savings from the program. Notably, there is no requirement that the discounted 340B price be passed on to uninsured patients who seek treatment at 340B entities. As a result, the 340B entity will acquire the drug at a discounted price, but the uninsured patient may pay the full list price for the drug. While some 340B entities pass savings on to uninsured patients, many use savings from the 340B program to pay for the operations of the covered entity, such as marketing.

In 2011, GAO issued a report on the savings generated by covered entities through the program.⁴⁴ While covered entities reported that 340B savings were used to expand access and services, GAO told Committee staff that all but one entity audited was unable to tell GAO the exact number of funds generated from the 340B program and how 340B funds were used. HRSA does not require covered entities to report the amount of funds generated from the 340B program, or how the entity spends those funds.

Further, there is little transparency surrounding the ceiling prices set by manufacturers in accordance with a statutory formula. Consistent with an HHS OIG recommendation, the ACA mandated that HRSA share ceiling prices with covered entities through a secure website. HRSA has since testified that it was unable to do so due to a lack of resources, but would undertake that project in 2015. However, covered entities still do not have access to that data. Without that data, covered entities are unable to ensure they are paying an appropriate price for 340B drugs. While HRSA has authority to establish a mechanism to share ceiling prices with 340B providers, HRSA does not have the authority to share ceiling prices with the states in order to enable state Medicaid agencies to ensure that they too are paying appropriate prices.

g. HRSA's Authority is Limited

HRSA has limited authority to regulate and enforce requirements for the 340B program. The three areas in which HRSA has explicit regulatory authority are calculation of 340B drug ceiling prices, imposition of manufacturer CMPs, and implementation of a dispute resolution process. As described above, lack of clarity on program requirements creates confusion as to what constitutes compliance, and further, HRSA lacks the authority to issue regulations clarifying those requirements.

In 2014, HRSA was preparing an omnibus regulation, which the agency said would have addressed a wide range of policy issues related to the program, including the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities. However, before the omnibus 340B regulation was released, HRSA found itself in litigation over a separate orphan drug regulation.⁴⁵ In May 2014, a ruling by the United States District Court for the District of

⁴⁴ Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO 11-836 (Sep. 2011).

⁴⁵ The orphan drug rule HRSA issued allowed 340B covered entities affected by the orphan drug exclusion (critical access hospitals, freestanding cancer hospitals, sole community hospitals and rural referral centers) to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation.

Majority Memorandum for July 18, 2017, Subcommittee on Oversight and Investigations Hearing
Page 13

Columbia vacated HRSA's orphan drug regulation in the 340B program on the grounds that HRSA lacks the statutory authority to engage in that form of rulemaking.⁴⁶

In June 2014, HHS/HRSA announced it continued to stand by its interpretation described in its published final rule, and in July, HRSA issued an interpretive guidance pertaining to the statutory requirement for inclusion of drugs with orphan drug designations in the 340B drug pricing program.⁴⁷ These agency actions were met with further litigation. In November 2014, with the ongoing litigation on the orphan drug regulation, HRSA withdrew its omnibus 340B regulation. The District Court's ruling vacating the regulation was affirmed in October 2015, and hampers HRSA's ability to issue regulations and to enforce provisions of the 340B program.

After HRSA withdrew its omnibus regulation, it subsequently released its proposed 340B Drug Pricing Program Omnibus Guidance, commonly referred to as the "Mega-Guidance" in August 2015.⁴⁸ However, HRSA withdrew the Mega-Guidance on January 30, 2017, shortly after the Trump Administration issued a regulatory freeze requiring agencies to retract any regulations currently under review.

In light of these issues, the Committee hopes to explore the challenges HRSA faces in conducting oversight of the 340B program, and the impact of the program on patients, providers, manufacturers, and other stakeholders.

IV. ISSUES

The following issues may be examined at the hearing:

- How has HRSA's oversight changed to reflect the growth of the 340B program in recent years?
- How effective is HRSA's oversight in detecting and resolving non-compliance with 340B program regulations?
- Does HRSA currently have the regulatory authority it needs to successfully oversee the 340B program?
- How has the 340B program affected patient care?

⁴⁶ *Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services*, Civil Action No. 2013-1501 (D.C. 2014).

⁴⁷ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *Program Requirements*, available at <http://www.hrsa.gov/opa/programrequirements/interpretiverule/>.

⁴⁸ Health Resources and Services Administration, U.S. Dep't of Health and Human Services, *340B Drug Pricing Program Omnibus Guidance*, available at <https://www.federalregister.gov/documents/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance>.

Majority Memorandum for July 18, 2017, Subcommittee on Oversight and Investigations Hearing
Page 14

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Brighton Haslett or Brittany Havens of the Committee staff at (202) 225-2927.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

August 4, 2017

Captain Krista M. Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Dear Captain Pedley:

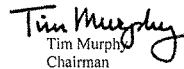
Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, July 18, 2017, to testify at the hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, August 18, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

House Energy and Commerce Committee
 Subcommittee on Oversight and Investigations
 Hearing entitled, “Examining HRSA’s Oversight of the 340B Drug Pricing Program”
 Questions for the Record
 September 26, 2017

The Honorable Tim Murphy

1. HRSA testified at our July hearing that one of the biggest issues it faces in administering and overseeing the 340B program is the vague definition of patient. In fact, GAO recommended in 2011 that HRSA clarify the definition of a 340B patient, and that recommendation currently remains open. Captain Pedley described HRSA’s attempts to tighten the definition of patient, one of the more recent attempts being the August 2015 omnibus guidance, in which HRSA addressed the ambiguity and tried to clarify that definition. HRSA received more than 1,200 comments related to the guidance, some of which were related to the definition of “patient.” I am interested in the comments related to the definition of “patient” and how HRSA has taken those comments into consideration.
 - a. What were the biggest take aways from the comments related to the ambiguous definition of “patient” and how will those comments affect HRSA’s approach to clarifying that definition?

HRSA issued a proposed 340B Omnibus Guidance in August 2015, which addressed key policy issues raised by various stakeholders to assist covered entities and manufacturers in their ability to satisfy 340B Program requirements and expectations, including the definition of a patient. The proposed guidance was open for review and public comment in the *Federal Register*.¹

Regarding the specific comments HRSA received on the definition of a patient, manufacturers generally supported the revised patient definition. Manufacturer groups also recommended that HRSA limit the term “patient” to the indigent, or those individuals lacking commercial or governmental insurance, or to those who otherwise have no outpatient drug coverage.

Covered entity commenters had concerns about HRSA’s authority to define the term patient, that the proposed definition was more restrictive than the 1996 patient definition guidance, and that many of those served by covered entities would no longer qualify as patients. The covered entities also expressed that a “one-size-fits-all” approach to the patient definition did not recognize the unique statutorily mandated structure and goals of certain categories of covered entities. All comments on the 2015 proposed Omnibus Guidance can be found on [regulations.gov](https://www.regulations.gov) at <https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=HRSA-2015-0002>.

- b. Were there any notable trends that HRSA saw in the comments related to the definition of “patient” and program compliance, such as the issue of drug diversion, that will affect HRSA’s work going forward?

¹ 80 FR 52300 (August 28, 2015)

The comments in the proposed 2015 Omnibus Guidance related to the definition of patient varied; there were no clear trends. HHS is working to determine next steps to address the policy issues included in the proposed Omnibus Guidance, which will inform our efforts to improve program compliance, including with regard to preventing drug diversion.

- 2. HRSA also testified at our July hearing that it tracked information regarding the growth rate for new child sites compared to new covered entities. On July 17, HRSA's website listed a total of 41,132 registered entities. As of August 4, HRSA's website lists 42,217 total registered entities—an increase of 1,085 registered entities since the hearing.**

- a. How many of the 1,085 new registered entities are unique covered entities and how many are child-sites?**

Currently, HRSA only designates hospital outpatient facilities and health center (and health center look-alikes) service delivery sites as child sites. All other registrations are considered parent sites. During the April 2017 registration period (with a start date of July 1), there were 37 new parent sites and 1,144 new associated/child sites registered under the Program. As of July 1, 2017, 12,470 covered entities and 28,276 associated/child sites participate in the 340B Program for a total of 40,746 registered sites. HRSA tracks this information on a quarterly basis and utilizes information from the previous quarter for our analysis.

- b. Overall, is HRSA seeing a faster growth rate for new covered entities or new child-sites?**

Since 2010, HRSA has continued to see an increase in both the number of parent and child sites for hospital outpatient facilities and health center sub-grantees, which are deemed child sites in the 340B database. This is due to a variety of factors, including the five new eligible hospital types that were added to the 340B statute in 2010, which increased the total number of hospitals eligible to participate in the program. In addition, for purposes of transparency, HRSA also instituted a new reporting policy in 2012 that required all hospital outpatient services and clinics that use the 340B Program to be listed on the HRSA database. That effort led to a large increase in the number of hospital sites that appeared on the 340B database. Many of those sites had been participating for years, but had not previously been required to register individually. The chart below provides additional information about the growth of 340B parent versus child site participants for hospitals and health centers.

340B Parent vs. Child Site Participants for Hospitals and Health Centers			
Date	Total Number of Participating Sites	Number of Parent Sites for Hospitals, Health Centers,	Number of Child Sites for Hospitals, Health Centers,

		and Health Center Look- Alikes	and Health Center Look- Alikes
July 2010	14,725	2,063	5,064
July 2011	16,572	2,744	6,135
July 2012	18,561	2,947	7,990
July 2013	22,641	3,190	11,791*
July 2014	26,870	3,318	15,408
July 2015	32,071	3,431	20,233
July 2016	36,914	3,609	24,843
July 2017	40,746	3,726	28,276
Source: Internal Analysis of HRSA 340B Database			
*In 2012, HRSA instituted a new reporting policy that required all hospital outpatient services and clinics that use the 340B Program to be listed on the HRSA database.			

The Honorable Michael C. Burgess

- 1. HRSA has taken specific steps to addressing duplicate discounts by creating the Medicaid Exclusion File (MEF), which providers can use to prevent duplicate discounts in Medicaid fee-for-service. Has HRSA undertaken any efforts to creating a similar MEF for Medicaid Managed Care?**

In December 2014, HRSA clarified that the current mechanism in place to prevent duplicate discounts, the Medicaid Exclusion File (MEF), was specific to Medicaid fee-for-service. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care. HRSA addressed this issue in its 2015 proposed Omnibus Guidance and is working to determine future policy in this area. In the meantime, HRSA is aware that some covered entities are working with managed care organizations (MCOs) and state partners to develop models for the prevention of duplicate discounts. HRSA encourages 340B covered entities to work with their states to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs. In addition, HRSA is working closely with the Centers for Medicare & Medicaid Services and other stakeholders to develop possible policy and technical solutions for how covered entities and states can prevent duplicate discounts for 340B drugs dispensed to MCO patients.

- 2. Upon delaying HRSA's most recent 340B rule, "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties and Regulations", the agency acknowledged that a delay of the rule was warranted because:**

"objections regarding the timing and challenges of compliance with the [Final Rule]... as well as other objections to the [Final Rule], may not have been adequately considered" such that HRSA should "engage in longer rulemaking" to "adequately consider" stakeholder comments, "consider questions of fact, law, and policy," "consider the regulatory burdens that may be posed," and "ensure that... the implementation of this rule... is coordinated with and takes into consideration overall 340B Program implementation."

- a. However, HRSA has not undertaken any apparent efforts to re-examine these substantive considerations. What is HRSA's plan to ensure that these considerations are reexamined?

To provide affected parties with sufficient time to make needed changes to facilitate compliance, on May 19, 2017, HRSA issued a final rule, which delayed the effective date until October 1, 2017.² HRSA recently proposed a further delay of the final rule's effective date to July 1, 2018, to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking.³

The Honorable Frank Pallone, Jr.

1. The 340B program is a critical component of the safety net. 340B drug discounts allow covered entities—such as community health centers, safety net hospitals, state and local health departments, family planning clinics, and AIDS drug assistance programs—to maximize scarce resources and provide comprehensive health services to vulnerable patients.

- a. Can you describe the types of comprehensive services that 340B covered entities provide?

There are many types of 340B covered entities that provide different services, though the 340B statute itself does not address the types of services that eligible entities provide. For example, HRSA's Health Center Program grantees provide comprehensive primary healthcare services. Health centers also often integrate access to pharmacy, mental health, substance abuse, and oral health services in areas where economic, geographic, or cultural barriers limit access to affordable healthcare services. As another example, HRSA's AIDS Drug Assistance Program (ADAP) grants provide medications to low-income people living with HIV who have limited or no health insurance coverage. ADAP funds may also be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments.

2. Hospitals, clinics, and other 340B covered entities rely on this program to provide essential healthcare services to needy populations. For the 340B program to function as intended, however, we must guarantee an appropriate amount of transparency and adequate oversight of both manufacturers and program participants. One such need for transparency relates to the 340B ceiling price that manufacturers charge covered entities. The Affordable Care Act (ACA) required HHS to share ceiling prices with covered entities, which would allow entities to ensure they are receiving the appropriate price for 340B drugs. HRSA has proposed a web-based system that would allow covered entities to view the 340B ceiling prices.

- a. What is the status of this system, and when will it be available for covered entities to access 340B ceiling prices?

² 82 FR 22893 (May 21, 2017)

³ 82 FR 39553 (Aug. 21, 2017)

Section 340B(d)(1)(B) of the Public Health Service Act requires HRSA to collect information from manufacturers to verify the accuracy of 340B ceiling prices, and then make ceiling prices available to covered entities. With prices for over 40,000 national drug codes, building such a system is extremely complex. Due to the proprietary nature of the pricing data, it is important to ensure that appropriate security safeguards are instituted.

In the process of developing the pricing system, HRSA sought to modernize the registration system database to enhance its functionality and security for both manufacturers and covered entities since the pricing system will interface with the data that is collected through registration. The new system, known as the 340B Office of Pharmacy Affairs Information System (340B OPAIS) will function as one system, and it will have two separate components—a new covered entity registration system and the new secure pricing system.

The new system will be released in a phased approach, beginning with the registration system in mid-September 2017. The pricing component of the new 340B OPAIS will be released at a later date.

3. **The Government Accountability Office's (GAO) 2011 report (GAO- 11-836) notes that the ACA established several important program integrity provisions for the 340B Program, and recommended that HRSA take additional steps to improve oversight of the program. In particular, GAO recommended that HRSA conduct selective audits of 340B covered entities for program compliance.**

- a. **How many audits has HRSA conducted to date, and how have these audits been effective in improving program integrity?**

Since FY 2012, HRSA has completed 844 audits (as of July 28, 2017), which included review of 11,281 outpatient facilities and 18,851 contract pharmacies. This includes 200 audits that HRSA conducted in FY 2017. HRSA has also taken steps to use audit results to create tools and resources to assist 340B participants in program compliance.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

August 4, 2017

Ms. Erin Bliss
Assistant Inspector General
Office of Evaluation and Inspections, Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, DC 20201

Dear Ms. Bliss:

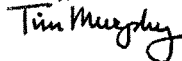
Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, July 18, 2017, to testify at the hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, August 18, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201



AUG 17 2017

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Chairman Murphy:

I am writing in response to questions for the record from Congressman Michael C. Burgess following my testimony before the Subcommittee on Oversight and Investigations on July 18, 2017, at the hearing entitled "Examining HRSA's Oversight of the 340B Drug Pricing Program."

If you have any questions, please contact me, or your staff may contact Jason Wittemen, Director of Congressional Affairs, at (202) 708-9755 or Jason.Wittemen@oig.hhs.gov.

Sincerely,

A handwritten signature in black ink that reads "Erin Bliss".

Erin Bliss
Assistant Inspector General
for Evaluation and Inspections

Enclosure

cc:
The Honorable Diana DeGette
Ranking Member, Subcommittee on Oversight and Investigations

Enclosure: Question for the Record

The Honorable Michael C. Burgess

1. The Office of Inspector General found in its report “State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates” that states can support efforts to prevent duplicate discounts from Medicaid Managed Care in the program through examining claims and exercising their own respective oversight of the program. The uptake, however, in this oversight has varied across the country. What incentives, if any, exist that would encourage states to exercise oversight of the program?

Office of Inspector General Response:

States have a couple of existing incentives to ensure that they can accurately identify 340B claims – an essential step in effectively preventing duplicate discounts for drugs paid by both fee-for-service Medicaid and Medicaid managed care organizations (MCOs). As we note in our June 2016 report, if States’ methods for identifying 340B claims are inaccurate, they risk forgoing rebates to which they are entitled – resulting in States essentially overpaying for drugs.¹ In addition, the findings of our August 2014 report reveal that Medicaid drug rebate disputes between States and manufacturers often relate to concerns about 340B-purchased drugs and potential duplicate discounts.² Accordingly, States have an incentive to accurately identify and exclude 340B claims in order to avoid such disputes, which can lead to inefficient use of State resources and jeopardize rebate payments from manufacturers.

¹ OIG, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430, June 2016.

² OIG, *Medicaid Drug Rebate Dispute Resolution Could Be Improved*, OEI-05-11-00580, August 2014.